

***ChemImage Corporation v.
Johnson & Johnson and Ethicon, Inc.***

24-cv-2646 (JMF)

Plaintiff ChemImage's Closing Argument

March 28, 2025

Ethicon's Descent Into Absurdity

**Ethicon
Claims:**

**CI proposed target
specific ignore labels**

Hansen Aff. ¶ 51; Lewis Aff. ¶ 67;
Tr. 964:14-964:18 (Hannafor)

**Didn't know "dashed"
lines meant ignore
labels**

Tr. 763:13-763:15 (Hansen); 930:16-
930:18 (Lewis)

**No more uncertainty
after EL5**

Tr. 929:9-929:16; 935:17-935:25 (Lewis)

**The
Record
Shows:**

**CC proposed usage of
target-specific
"uncertainty labels"
in 2021**

PX-462

**ETH and CC saw hundreds
of dashed lines with
ignore labels during
video review**

PX-429; PX-867; Tr. 930:19-930:22
(Lewis); 846:3-846:6 (Hansen)

**There is always some
uncertainty**

Tr. 758:5-758:7 (Hansen);
948:17-19 (Lewis);
A. Saltman Aff. ¶23

Ethicon's Descent Into Absurdity

**Ethicon
Claims:**

**General ignore is okay
but target-specific
is not**

Hansen Aff. ¶ 51; Lewis Aff. ¶ 67

**The
Record
Shows:**

**General and target-
specific are treated the
same in scoring**

PX-462

**Did not know about
target specific ignore
labels in obscured
scenes**

Hansen Aff. ¶ 106; Tr. 737:11-737:14 (Hansen)

**All target specific
ignore in obscured
scenes had to be
approved by DRB**

Tr. 790:12-790:14 (Hansen)

**Dr. Aksoy explains target-
specific ignore labels in
obscured scene to CC as
early as October 5, 2022**

PX-378

**DRB only reviewed 27 files
out of 881 files from the
VAB Final Report. ETH was
sitting on all the data**

Tr. 824:7-824:15 (Hansen);
814:8-13 (Hansen)

Roadmap of the Presentation

I. JSC Milestone Determination

II. Scope of the Termination Letter

III. Ethicon Failed to Prove Breach

IV. Linkage Scenarios

V. Tortious Interference

VI. IP Impairment Damages

**Ethicon's Failure to Convene the JSC,
Without More, Is an Independent Basis on
Which to Grant Judgment to ChemImage
for Ethicon's Breach of Contract.**

The Agreement Set the Milestone Requirements

Exhibit B

2. Development Milestone Payment Schedule and Terms

No.	Development Milestone Payment Descriptions	Milestone Payment Amount
1	Development Milestone 1A: Successful in vivo Demonstration of CI Visualization System for Critical Structures Identification Functionality	\$ 5,000,000
2	Development Milestone 1B: Successful in vivo Demonstration with Modified JNJ Visualization System for Critical Structures Identification Functionality	\$ 2,500,000
3	Development Milestone 1C: EndoVere Critical Structures Identification Functionality Visualization Chartering Approval	\$ 2,500,000
4	Development Milestone 2A: Successful in vivo Demonstration of CI Visualization System for Cancer Localization Functionality	\$ 8,000,000
5	Development Milestone 2B: Successful in vivo Demonstration with Modified JNJ Visualization System for Cancer Localization Functionality	\$ 2,500,000
6	Development Milestone 2C: EndoVere Cancer Localization Functionality Visualization Chartering Approval	\$ 2,500,000
Total		\$23,000,000

- b. The approval criteria for each Development Milestone is identified in Exhibit B-1 to this Agreement.

EXECUTION VERSION
Confidential

RESEARCH, DEVELOPMENT, LICENSE AND COMMERCIALIZATION
AGREEMENT

by and between

ChemImage Corporation

and

Ethicon, Inc.

CONFIDENTIAL

PX-1

DEF_00559404
Page 1 of 104

12/27/19 Definitive Agreement (PX-1)

PX-1 at 55-56

The Agreement Outlines the Milestone Acceptance Criteria

Exhibit B-1

DEVELOPMENT MILESTONE ACCEPTANCE CRITERIA

1. Preamble

The intent of this Exhibit is to address approval criteria related to milestones 1a, 1b, 1c, 2a, 2b, and 2c. These Development Milestones (Exhibit B, Section 2) are grouped into three Milestones related to Critical Structure Identification Functionality and another three milestones related to Cancer Localization Functionality. Each of the groups of three consist of Milestones: a.) - successful in-vivo demonstration using CI visualization system), Milestone; b.) – successful in-vivo demonstration using prototype J&J/Ethicon visualization system, and Milestone; and c.) – charter approval.

The intent of this Exhibit is to further provide detailed approval criteria for each Development Milestone, as a set of clear guidelines, expectations, method and tools definitions and otherwise quantify criteria of success.

As laid out in the sections below, the Exhibit will address each Milestone separately, while common and related items are listed here as a part of the preamble. The Deliverable must meet all Functional Success Criteria and Technical Detection Success Criteria in order for the applicable development Milestone to be met.

3. **Milestone 1b** – Successful in-vivo demonstration with a prototype J&J/Ethicon Visualization System of Critical Structure Identification Functionality.

Milestone Description: Integrate the CI technology into a prototype J&J Visualization system and use the resulting system to demonstrate real-time in-vivo detection of critical structures when buried in up to 5mm of tissue and characterize the system's ability to detect up to 10mm. At the end of this milestone, a demonstration of the detection capabilities outlined below will be held at Ethicon, for the core team. A report will be delivered outlining how the technology successfully achieved the Milestone.

Functional Success Criteria:

Successful Detection (On a scene by scene basis within the final testing protocol):

- Sensitivity $\geq 80\%$
- Specificity $\geq 80\%$
- Area Under the ROC Curve (AUC) ≥ 0.80
- Characterize opportunities and tradeoffs for higher sensitivity and specificity

PX-1 (Definitive Agreement) at 58, 59

PX-1 (Definitive Agreement) at 62

The Agreement Delegated Authority Exclusively to the JSC to Determine Whether the Milestones Were Met



Definitive Agreement (PX-1)

2.4. Joint Steering Committee.

2.4.1 **Composition and Purposes.** CI and Company will establish a Joint Steering Committee (the “JSC”) which will consist of two CI members and two Company members, each of whom shall be senior employees authorized to make the decisions for its respective Party allocated to the JSC set forth immediately below. The JSC shall only be responsible for the following:

(a) to adjust the Development Timeline, Milestones and the Launch Deadline, as necessary in its sole discretion, to further the goals of the Development Program;

(b) to determine whether the Milestones specified in Exhibit B have been met;

PX-1 (Definitive Agreement) at 15-16

JSC Decisions Had to Be Unanimous

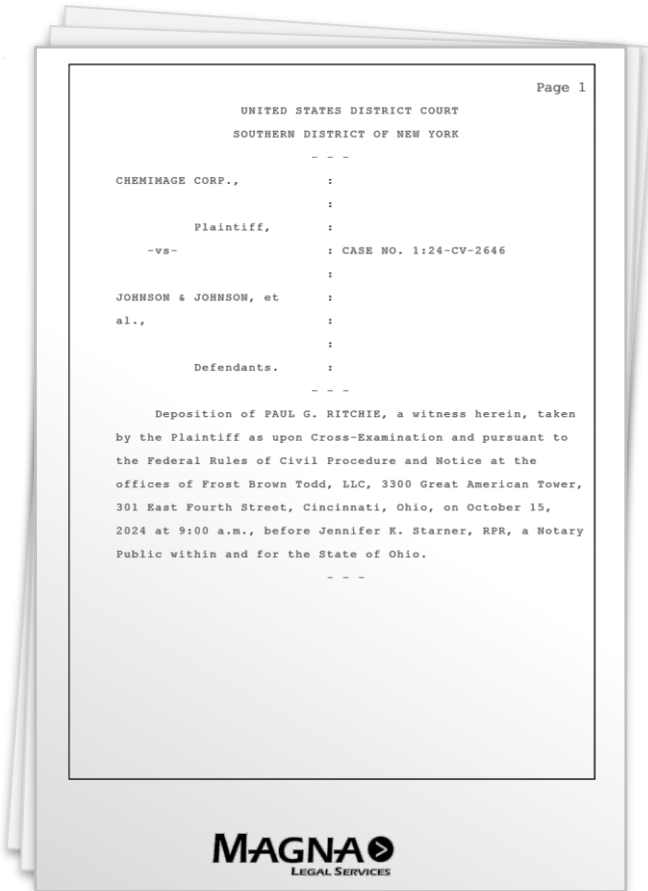


2.4.3 Voting and Deadlocks. The CI members shall collectively have one (1) vote on the JSC, and the Company members shall collectively have one (1) vote on the JSC. Decisions of the JSC shall be made by unanimous vote.

PX-1 (Definitive Agreement) at 17

Definitive Agreement (PX-1)

Ethicon JSC Member, Paul Ritchie, Admits That Ethicon Could Not Unilaterally Determine Milestones



**“[N]either party could
unilaterally determine whether
a Milestone was met.”**

Ritchie Dep. Tr. 41:23-42:17



Paul Ritchie
*Director of Advanced
Visualization, Ethicon (Ret.)
& Project Erie JSC Member*

10/15/24 Deposition of Paul Ritchie

Ethicon's Absurd Argument: JSC Immediately Ceded Its Power to Ethicon



Tamara Lanier

Director, Sales Excellence
and Enablement, Ethicon &
Project Erie JSC Member

"At the initial kickoff meeting on January 29 and 30, 2020, the parties specified the process for this approval and clarified that for development milestones 1A, 1B, 2A, and 2B, ChemImage would present a report to ***Ethicon***, who ***would determine whether the report demonstrated that the milestone criteria had been satisfied.***"

Lanier Aff. (PX-1018) ¶158.

Ethicon's Absurd Argument: JSC Immediately Ceded Its Power to Ethicon



1/29/20 – 1/30/20 Erie Program Kickoff Meeting
(DX-301)

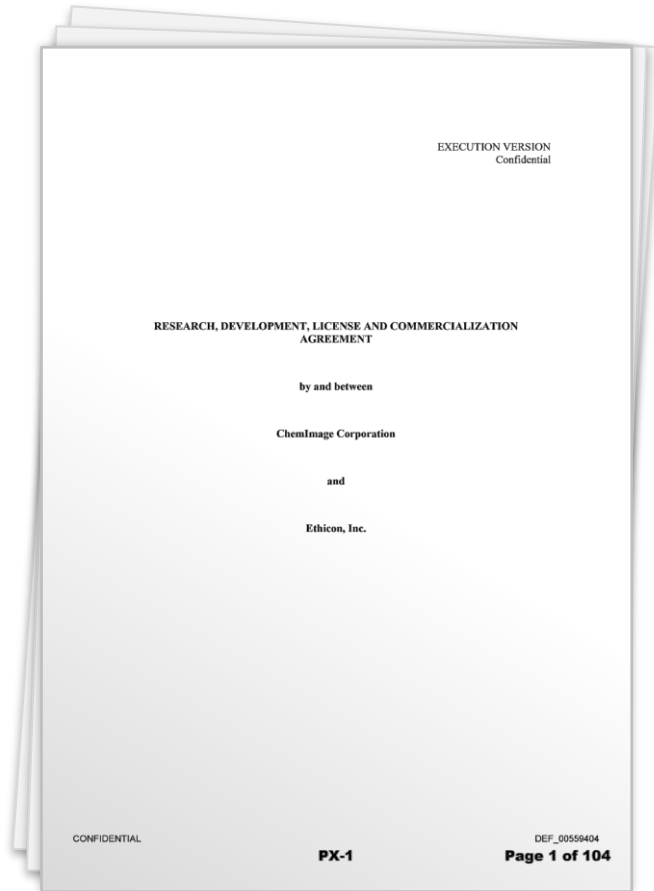
Task 3 – Erie Multispectral Endoscope in vivo Tests

Task 3.4 – 3.5 – Milestone 1B

- Task 3.4 – Milestone 1B Executive Review
 - Erie Team prepares a summary of the in CS in vivo test results and submits to Ethicon executive leadership for review
 - Ethicon executive leadership verifies that the test results meet the established milestone success criteria for Milestone 1B
 - Ethicon executive leadership declares that the Milestone has been met and payment to ChemImage can be made
- Milestones & Deliverables
 - Milestone 1B
- Key Dates
 - Milestone 1B Executive Review 3Jun2021
- Task 3.5 – Milestone 1B in vivo Test of Modified PimientoSB for CS
 - Milestone has been achieved
- Milestones & Deliverables
 - Milestone 1B In Vivo Test of MCI for CS
- Key Dates
 - Milestone 1B In Vivo Test of Modified PimientoSB for CS 3Jun2020

DX-301 at 213

The Parties Never Amended the Agreement to Replace the JSC With Ethicon



12.14. Entire Agreement. This Agreement constitutes and contains the complete and final understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties relating to the matters referred to herein, and may only be amended by a written document, duly executed on behalf of the respective Parties.

PX-1 at 48

Definitive Agreement (PX-1)

Ethicon's JSC Member Admits: The JSC Met and Approved Milestone 1A



Paul Ritchie

*Director of Advanced
Visualization, Ethicon (Ret.)
& Project Erie JSC Member*

Q. And Milestone 1a was submitted to the JSC for approval, right?

A. That's correct.

Q. And the JSC approved Milestone 1a?

A. Ultimately, yes, with some caveats.

Q. So yeah. Just want to summarize and then we'll go back. **So with respect to Milestone 1a, the JSC agreed to a milestone acceptance criteria, ChemImage submitted final and draft reports. Then those reports were reviewed by Cambridge and Ethicon. And then Milestone 1a was approved by the JSC. Do I have that right?**

A. Those are the steps that I recall taking place. There was -- after the review by the JSC and before the final approval, there were other discussions about some of the perceived shortcomings of that work.

Q. Okay.

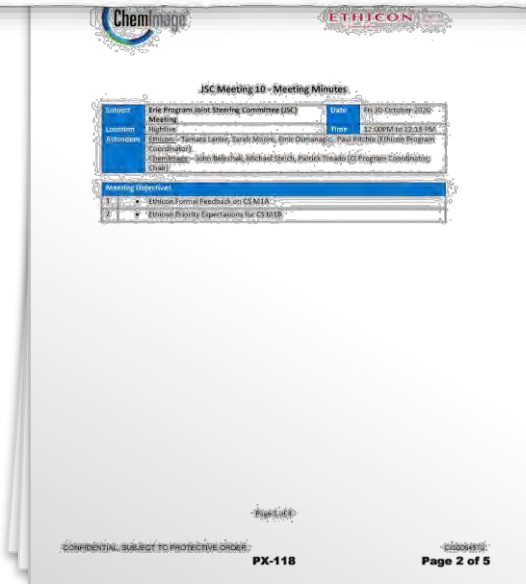
A. So there's just a step in there that you skipped, but other than that, I think it's correct.

Ritchie Dep. Tr. 63:20-64:17

The JSC Convened to Review & Approve Milestone 1A

JSC Meeting 10 - Meeting Minutes

Subject	Erie Program Joint Steering Committee (JSC) Meeting	Date	Fri 30-October-2020
Location	Highfive	Time	12:00PM to 12:18 PM
Attendees	Ethicon – Tamara Lanier, Sarah Moore, Emir Osmanagic, Paul Ritchie (Ethicon Program Coordinator) ChemImage – John Belechak, Michael Steich, Patrick Treado (CI Program Coordinator, Chair)		



10/30/20 JSC Meeting Minutes
(PX-118)

1	Ethicon Review of M1A Results <ul style="list-style-type: none">Paul Ritchie provided an overview of M1A:<ul style="list-style-type: none">Overall, progress has been made as part of Milestone 1A. The team has identified areas of concern coming out of the M1A report. The objective of sharing these learnings is to ensure that we can address them in Milestone 1B and the joint team will be successful.Performance:<ul style="list-style-type: none">Limited evidence against depth of detection (characterize detection capabilities at 5-10mm) and performance degradation with obscurations starting at ~2-4 mm.Limited evidence against simultaneous multi-target detection and discriminationShortcomings of object-based performance were highlighted by differing perceptions of the technology as evidenced by pixel based vs. object-based scoring.PPV performance raised concerns especially when full dataset was included and under obscurationData Practices<ul style="list-style-type: none">Data selection criteria was overly constrainedSampling 19 out of the total 240 data population is ~8% of total data. Additionally, choosing only ~10% of video frames constitutes roughly ~1% of total available data.Performance presented for milestone acceptance was achieved by selecting the best performing recipes for each targetPaul Ritchie stated that M1A will be moved forward for payment, and concerns from M1A would be jointly addressed in M1BPatrick Treado agreed on behalf of ChemImage
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Ethicon's JSC Member Admits: The JSC Met and Approved Perfusion



Paul Ritchie

*Director of Advanced
Visualization, Ethicon (Ret.)
& Project Erie JSC Member*

Q. You were part of the Ethicon team that evaluated whether Milestone 1A had been satisfied and also evaluated a final report from ChemImage on perfusion?

A. That's correct.

Q. Okay. And was it your understanding at the time, doing those reviews, that ... to the extent the milestone was not satisfied based on a final report, ChemImage would have an opportunity to do a rework to resolve issues raised by Ethicon?

A. Yeah.

Ritchie Dep. Tr. 67:5-14

Q. And **after Ethicon had reviewed the perfusion component portion of Milestone 1b**, the JSC -- **there was a meeting at the JSC and the JSC agreed to approve the perfusion component of Milestone 1b?**

A. That's correct.

Tr. 94:4-9 (Ritchie)

The JSC Convened to Review & Approve the Perfusion Portion of Milestone 1B

JSC 2022 Meeting 02 - Meeting Minutes

Subject	Erie Program Joint Steering Committee (JSC) Meeting 2022 01	Date	Wednesday 09-Mar-2022
Location	Highfive, Blue Ash, OH	Time	3:00PM - 4:00PM
Attendees	Ethicon –Francesc Fernandez (Observer), Tamara Lanier, Paul Ritchie (Ethicon Program Coordinator) ChemImage – Carl Denys (Observer), Martin Madden, Patrick Treado (CI Program Coordinator, Chair)		

Meeting Objectives
1. To Review Urgent Business
2. To Review Standing Business
3. To Review New Business
4. To Review Action Items & Next Meeting Agenda

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HIGHLY CONFIDENTIAL-ATTORNEY EYES ONLY

PX-356

DEF 00736881
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ETHICON

Endovascular
Thrombectomy
Systems

Meeting Minutes

Agenda Items Discussed		
No.	Agenda Topic	Highlights
1	CS M1B Perfusion Approval	• Delivery & Approval Summary: Pat Treado (PT) shared the Perfusion Approval of M1B Perfusion and asked about any resulting implications. • Implications Discussion: Paul Ritchie (PR) & Tamara Lanier (TL) shared it was a Great Win and a 1 st Step on a Journey. No immediate implications but Leads the team to Critical Targets for the year. ChemImage is in alignment with this assumption.
2	2022 Erie Program Priorities	• Critical Structure Discussion: PT shared the EDC CLCs & Program Quarterly Goals. PT shared teams are at risk that it's heading the end of Q1 and teams are awaiting alignment on the High Level Goals for the year. PT asked that players have their Blue Air next level aligned to achieve. Vincent Fernandez (VF) asked what axes and goals are not in the program? PT shared the team isn't as aligned on Cancer Localization Program as a whole. Since the slope designate "going in" appears teams are close, but still need final alignment. • Cancer Localization Discussion: PT shared the Red Kinds Cancer Localization plan that lead to a body of metrics to track and CLC MAs for 2022. PT shared the teams need to align and get clarity on the M2 pathway for 2022. PT asked for clarity on Cancer localization from Ericson view. VF asked about

Agenda Items Discussed

No.	Agenda Topic	Highlights
	Urgent Business	
1	CS M1B Perfusion Approval	<ul style="list-style-type: none">Delivery & Approval Summary: Pat Treado (PT) shared the Perfusion Approval of M1B Perfusion and asked about any resulting implications.Implications Discussion: Paul Ritchie (PR) & Tamara Lanier (TL) shared it was a Great Win and a 1st Step on a Journey. No immediate implications but Leads the team to Critical Targets for the year. ChemImage is in alignment with this assumption.

3/9/2022 JSC Meeting Minutes
(PX-356)

PX-356 at 8

The JSC Convened to Review & Approve the Perfusion Portion of Milestone 1B

JSC has reviewed/approved CS M1B Perfusion Delivery;

Erie Program

MGPP Category	Milestone	Original DA	New Allocation	Sc1 Value	CI Delivery Date	ETH Approval Date	Payment Date	Modification Rationale
CS	M1A	\$ 5,000,000	100%	\$ 5,000,000	2-Oct-20	12-Nov-20	20-Nov-20	Original Scope (Defined in DA); No Modification Needed
CS	M1B	\$ 2,500,000	0%	\$ -				
CS	M1B Perfusion	\$ -	16.7%	\$ 416,667	14-Jan-22	11-Feb-22	30-Apr-22	JSC has reviewed/approved CS M1B Perfusion Delivery; \$ Amount Subject to DA
CS	M1B V	\$ -	16.7%	\$ 416,667	16-Nov-22	16-Dec-22	31-Dec-22	Delivery Date Subject to Program Schedule; \$ Amount Subject to DA
CS	M1B A	\$ -	16.7%	\$ 416,667	16-Nov-22	16-Dec-22	31-Dec-22	Delivery Date Subject to Program Schedule; \$ Amount Subject to DA
CS	M1B U	\$ -	16.7%	\$ 416,667	16-Nov-22	16-Dec-22	31-Dec-22	Delivery Date Subject to Program Schedule; \$ Amount Subject to DA
CS	M1B B	\$ -	16.7%	\$ 416,667	16-Nov-22	16-Dec-22	31-Dec-22	Delivery Date Subject to Program Schedule; \$ Amount Subject to DA
CS	M1B N	\$ -	16.7%	\$ 416,667	16-Nov-22	16-Dec-22	31-Dec-22	Delivery Date Subject to Program Schedule; \$ Amount Subject to DA
CS	M1B Priority	\$ -	0.0%	\$ 4,000,000	16-Nov-22	16-Dec-22	31-Dec-22	Align Incentives to M1B Highest EP Priority
CS	M1C	\$ 2,500,000	100%	\$ 2,500,000	16-Feb-23	18-Mar-23	23-Mar-23	Delivery Date Subject to Program Schedule; \$ Amount Defined in DA
CL	M2A	\$ 8,000,000	0%	\$ -				
CL	M2A Murine in vivo	\$ -	40%	\$ 2,000,000	30-Aug-22	29-Sep-22	4-Oct-22	Delivery Date Subject to Program Schedule; \$ Amount Subject to DA
CL	M2A Human ex vivo	\$ -	10%	\$ 500,000	30-Aug-22	29-Sep-22	4-Oct-22	Delivery Date Subject to Program Schedule; \$ Amount Subject to DA
CL	M2A Porcine ex vivo	\$ -	10%	\$ 500,000	30-Jun-22	30-Jul-22	4-Aug-22	Delivery Date Subject to Program Schedule; \$ Amount Subject to DA
CL	M2A Porcine in vivo	\$ -	40%	\$ 1,000,000	16-Nov-22	16-Dec-22	21-Dec-22	Delivery Date Subject to Program Schedule; \$ Amount Subject to DA
CL	M2B	\$ 2,500,000	100%	\$ 2,500,000	16-Sep-23	16-Oct-23	21-Oct-23	Delivery Date Subject to Program Schedule; \$ Amount Defined in DA
CL	M2C	\$ 2,500,000	100%	\$ 2,500,000	16-Oct-23	15-Nov-23	20-Nov-23	Delivery Date Subject to Program Schedule; \$ Amount Defined in DA
	TOTAL	\$ 23,000,000		\$ 23,000,000				

3/9/22 JSC Meeting
2 Presentation
(PX-410)

PX-410 at 11

Ethicon's Previous Attempts to Override the JSC Were Rebuffed

April 6, 2022

Subject: Erie Team Dynamics – Emir Osmanagic

Dear Francesc:



Dr. Patrick Treado, Founder and President
ChemImage Corporation
7325 Penn Ave., Suite 200
Pittsburgh, PA 15208

April 6, 2022

Francesc Osmanagic, VP R&D (Capital R&D/Advanced Imaging)
Ethicon, Inc.
40 S. Highway 92 West
Spencerville, IN 47460

Subject: Erie Team Dynamics – Emir Osmanagic

Dear Francesc:

As discussed at the Joint Steering Committee ("JSC") 2022 Meeting, held on Monday, March 28, 2022, and as you requested, I am writing to provide you information regarding the behavior of Ethicon employee Emir Osmanagic during our interactions under the Research, Development, License, and Commercialization Agreement dated as of December 27, 2019 (the "Agreement").

In the past two years, we have experienced multiple interactions with Dr. Osmanagic that have posed challenges to our team dynamics and interfered with our daily operations, program discipline, and team morale. These interactions have increasingly undermined ChemImage's ability to collaborate effectively and take full advantage of the strong working relationship we otherwise believe exists between our two companies. We are concerned that the challenging behavior of Dr. Osmanagic may risk the overall success of the program, and we share these incidents with you to avoid these challenges in the future.

Here are some specific examples of these interactions:

3. On September 5, 2020, during the Clinical Structure (CS) Milestone 1A (M1A) Run Study at Ethicon's Blue Ash Pre-Clinical Test Facilities, Dr. Osmanagic met with Dr. Patrick Treado to review the data selection process being followed as part of the Run Study. As that meeting, Dr. Osmanagic requested ChemImage provide speed inhibition performance or data that was being excluded from evaluation under the Acceptance Protocol. When Dr. Treado sought clarification on the use of the excluded data detection performance, Dr. Osmanagic represented that Ethicon would not have evaluation of Acceptance of CS M1A based on excluded data. Dr. Osmanagic's representation from the September 5, 2020 meeting were reviewed by the JSC at the October 30, 2020 JSC Meeting.

7325 Penn Ave., Suite 200 Pittsburgh, PA 15208 | Tel: 412-281-0835 | Fax: 412-281-0811

Page 3

In the past two years, we have experienced multiple interactions with Dr. Osmanagic that have posed challenges to our team dynamics and interfered with our daily operations, program discipline, and team morale. These interactions have increasingly undermined ChemImage's ability to collaborate effectively and take full advantage of the strong working relationship we otherwise believe exists between our two companies. We are concerned that the challenging behavior of Dr. Osmanagic may risk the overall success of the program, and we share these incidents with you to avoid these challenges in the future.

* * *

- On May 3, 2021, Dr. Osmanagic stated in an email to Mr. Steich that Milestone 1A of the Agreement had not been "fully completed." Both Ethicon and ChemImage had acknowledged the completion and acceptance of Milestone 1A during the JSC meeting of October 30, 2020 (JSC Meeting 10), with Ethicon feedback and summary uploaded to Sharefile on October 29, 2020. Upon receipt of the May 3, 2021 email, Dr. Treado spoke to Mr. Paul Ritchie of Ethicon on May 6, 2021 to address Dr. Osmanagic's comments. On May 6, 2021, Mr. Ritchie confirmed that Milestone 1A had been met in an email to Dr. Treado and stated that he would address the matter with Dr. Osmanagic directly. Dr. Osmanagic then sent an email on June 9, 2021 confirming acceptance of Milestone 1A. In this incident Dr. Osmanagic provided an incorrect representation of a critical milestone agreement contrary to his supervisor's recognition of the Milestone being met, as Milestone acceptance is the responsibility of the JSC.

4/6/22 Ltr from Treado to Fernandez
(PX-310)

PX-310 at 1, 3

The Parties Expected to Convene the JSC to Determine Milestone 1B

Erie Program CS M1B Critical Structures Acceptance Protocol Rev2 (23-June-2022)



Erie Program
Joint Steering Committee (JSC)
2022 Meeting 6

June 28, 2022

June 28, 2022

Erie Program CS M1B Critical Structures Acceptance Protocol Rev2 (23-June-2022)	
Technology	Demonstrate: <ul style="list-style-type: none">Critical Structure Targets: Veins, Arteries, Nerve, Bile Duct, Ureter - Mean of Sensitivity, Mean of Specificity, Mean of AUC > 80% AND Mean PPV, Mean NPV > Thresholds Determined by Prevalence @ 80% Sensitivity & SpecificityMulti-Target: Mean of Sensitivity, Mean of Specificity, Mean of AUC > 80% AND Mean PPV, Mean NPV > Thresholds Determined by Prevalence @ 80% Sensitivity & SpecificityObscuration: 0.5 mm natural and simulated with fat (or collagen)
	Detection Performance Metrics: <ul style="list-style-type: none">Obscuration: > 10 mm natural and simulated with fat (or collagen)80% Critical structure detection with recommendations & plan for improvementScore Assessment: Critical structure detection with movement
	Notes: <ul style="list-style-type: none">Results to be presented stratified separately per critical structure, multi-target combination, obscuration level, Target DimensionCharacterize % of cases where (Sensitivity > 80%, Specificity > 80%, PPV > 80% & NPV > 80%) = YESCharacterize ability and tradeoffs for higher sensitivity or specificity
Reusability	<ul style="list-style-type: none">Data to be presented in a statistically significant manner across full data set (consistent cases) and compared with Ethicon StandardStatistical analysis to be run on all collected data sets except where data must be excluded (Data exclusion to be aligned on jointly)
Technology	<ul style="list-style-type: none">Pixel based analysisPost processed statistical summaryReal time demonstration in Run Prep & Run Labs with detection and overlayMust allow user to operate under RGB light (or white light) while also detecting the critical structures using the GEIIR technologyCritical structure detection regions must be mutually independent and not overlap with one another or with perfusionNo target labeling-based calibration allowed, should be built into algorithmAllowed to auto expose calibration between targets/locations/casesMin 10 Wits test CS: Characterize ability and tradeoffs to minimize wavelengths as a function of performance
Predictorial Model	<ul style="list-style-type: none">Critical Structure Targets:<ul style="list-style-type: none">VeinsArteriesNervesBile DuctUreterMulti-Targets: UV, UA, UN, AV, AN, BA, BN, ANN, UAN, UANObscuration Model: GallagneyAdipose
Internal Feedback & External VOC	<ul style="list-style-type: none">Internal Feedback and External VOC Goals:<ol style="list-style-type: none">Receive feedback on ability to detect critical structures individually (NAIUM)Receive feedback on ability to detect multiple critical structures in the same scene (NAIUM)Receive feedback on ability to detect multiple observed critical structures (EAS & Ethicon)Internal Feedback Participants: Ethicon Free Leadership and 3 Internal surgeons to review protocol and detection results and provide feedbackExternal VOC Participants: 2 external surgeons
Approvals	<div>Review VOC Results & Detection Performance Metrics</div> <ul style="list-style-type: none">External 3rd Party Cambridge Consultants ReviewJSC Review & ApprovalInternal Ethicon Leadership Review & Approval

Draft For Working Team Only

6/28/22 JSC Meeting Presentation
(DX-304)

Approvals

Review VOC Results & Detection Performance Metrics

- External 3rd Party Cambridge Consultants Review
- JSC Review & Approval
- Internal Ethicon Leadership Review & Approval

DX-304 at 21

The Parties Expected to Convene the JSC to Determine VAB



2/28/23 JSC Meeting Presentation
(DX-284)

JSC 2023 Meeting 01

Erie Program JSC 2023 Meeting 01 Approval of JSC 2023 Meeting 01 Minutes			
Time	Topic	Discussion Points	Action Items
12:00 PM	Open Session	<ul style="list-style-type: none">Review Program Plan, high level quarterly objectives, goals, benchmarksFocus on Q1: Looking for alignment ETR/CI teams, then present to JSCUpdate on VABDiscussed along in the performance metrics calculations/ ignore labels - minor impact on resultsDiscussed the VAB pathway	<ul style="list-style-type: none">Will continue to involve Nancy and Rachel in UN discussions going forwardWill review the VAB report after SW issues are fixed
12:30 PM	Urgent Business	<ul style="list-style-type: none">CI and ETR are aligned with the development planInternal ETR review is still underwayPlanning to be done with them and release by end of Q1/23VOC report - should be out in JanuaryAlgorithm review - should be ready in JanuaryScope of work - ETR legal is working on this (ready in Feb)	<ul style="list-style-type: none">Algorithm review/working will be discussed at today's JSC meeting (above)
12:40 PM	Standing Business	<ul style="list-style-type: none">Chaired to close the outstanding 2022 JSC meeting minutesETR - "not consensus" not worth approvingCI - Not a requirement but something we've done as partners with JSC as the decision-making body, capture decisions made	<ul style="list-style-type: none">Mark previous (2022) minutes as "no consensus" to close them outMove forward (2023+) with the one-slide summary and review/approve going forward - put them in the body of the email to simplifyWill try this method and adjust if it isn't working
12:50 PM	New Business	<ul style="list-style-type: none">One teacher baby sat Saturday, and is now on leaveSeveral people were invited to stay for the closed session, JSC members agreed to discuss the closed session and local site noise meeting as Open Session	<ul style="list-style-type: none">Adjust the standing JSC meeting template to have the minutes review/acceptance for ETR
12:55 PM	Action Item Review & Next Meeting Agenda Discussion	<ul style="list-style-type: none">Next JSC meeting date 2/28/25 @ 12pm accepted	<ul style="list-style-type: none">Sketch for add Rachel and Nancy to the JSC while the SW issues are fixedSketch will modify the JSC rules and minutes templates accordingly

DX-284 at 4

Erie Program JSC 2023 Meeting 02 Agenda

Meeting Objectives

- Approval of JSC 2023 Meeting 1 Minutes
- VAB Update
- UN Path
- 2023 Annual Marketing Plan
- To review Urgent / Standing / New Business

DX-284 at 2

Key Decisions Taken

- Will continue to involve Nancy and Rachel in UN discussions going forward
- Will revise the VAB report after SW issues are fixed
- Mark previous (2022) minutes as "no consensus" to close them out
- Move forward (2023+) with the one-slide summary and review/approve going forward - put them in the body of the email to simplify
 - Will try this method and adjust if it isn't working
- Modify the standing meeting agenda to review, modify, approve the previous meeting's minutes at the beginning of the JSC Meeting

Key Agenda Items:

- VAB final report approval
- Review 2023 annual marketing plan

Ethicon Rebuffed ChemImage's Attempts to Convene the JSC to Review the VAB Final Report



Dr. Patrick Treado

*Founder & President, ChemImage
& JSC Member, Project Erie*

"Instead of a formal JSC meeting to review the VAB Final Report, Tamara Lanier asked ChemImage to have a shorter "touchpoint" for the February 28, 2023 JSC meeting ... although there was a JSC meeting scheduled for March 7, 2023, which was supposed to be the meeting during which the JSC would formally review the VAB Final Report and vote on the milestone, Ethicon declined the meeting invitation."

Treado Aff. (PX-1023) ¶ 69

Q. Okay. Had ChemImage requested a meeting of the JSC?

A. Yes.

Q. And how did Ethicon respond to that request?

A. We had requested a meeting on February 28th, which Ethicon requested be converted to a touch point meeting. And we had at the February 28th meeting scheduled a meeting for the end of March, but there was a meeting that was actually on the calendar for March 7th.

Q. And what happened with that meeting that had been on the calendar for March 7th?

A. ChemImage attended the meeting, Ethicon JSC members did not attend.

Tr. 130:21-131:7 (Treado)

Ethicon Avoided Meeting With ChemImage to Discuss the VAB Final Report



Tamara Lanier

*Director, Sales Excellence and Enablement,
Ethicon & Project Erie JSC Member*

Q. Why didn't you participate in the JSC meeting on March 7, 2023?

A. **Well, [Ethicon] had sent a termination letter on the 6th, and ... if we are terminating the agreement, then there is no need for the JSC itself to meet because there is nothing to govern.**

Tr. 546:3-9 (Lanier)

From: Lanier, Tamara [ETHUS] <TLanier@its.jnj.com>

Sent: Monday, February 27, 2023 3:23 PM

To: Patrick J. Treado <treado@chemimage.com>; Carl Denys <denysc@chemimage.com>

Cc: Michael Steich <steichm@chemimage.com>; Fernandez, Francesc [ETHUS] <FFerna40@ITS.JNJ.com>

Subject: Update requested: February 2023 JSC Monthly Meeting

Hi Carl & Pat,

I wanted to reach out regarding tomorrow's JSC meeting to request that we shift the format to a shortened JSC touchpoint vs. our formal Monthly JSC meeting format with slides and presentation content.

Since Francesco and I were both on vacation last week, our initial interactions with the Ethicon team this morning have surfaced multiple questions that should be addressed on a JSC level as soon as possible. However, at this point, we acknowledge that more time is required to appropriately prepare to engage in the necessary discussions and decision-making.

As such, we recommend that we have a 20-30min JSC touchpoint on Tuesday February 28th and then re-schedule the more comprehensive and formal JSC monthly meeting.

PX-41 at 1

Section 2.4.3(b): JSC Deadlock Leads to Binding Arbitration



Definitive Agreement (PX-1)

2.4.3 Voting and Deadlocks. The CI members shall collectively have one (1) vote on the JSC, and the Company members shall collectively have one (1) vote on the JSC. Decisions of the JSC shall be made by unanimous vote.

(a) In the event a deadlock occurs involving a matter that does not require modification of the Development Plan, the JSC shall attempt to resolve such deadlock for a period of thirty (30) days by engaging in good faith discussions. If such deadlock is not resolved after such thirty (30) day period, then each Party shall have the final decision-making authority with respect to the conduct of specific activities allocated to it under the Development Plan.

(b) In the event a deadlock occurs with respect to a modification of the Development Plan, the JSC shall attempt to resolve such deadlock for a period of thirty (30) days by engaging in good faith discussions. In the case of a JSC deadlock after such period, the issue will be escalated to the Head of Digital Surgery of Company and to the Chief Executive Officer of CI for resolution for a period of fifteen (15) days. If the issue cannot be resolved after such combined forty-five (45) day period, either Party may refer the unresolved matter for binding arbitration pursuant to Section 12.9 of this Agreement.

The Parties Understood That a JSC Deadlock on a Milestone Determination Would Lead to Arbitration



Dr. Patrick Treado

Founder & President,
ChemImage; JSC Member



Steen Hansen

Director, Advanced
Visualization Technologies &
Project Erie Technical Lead

CS VAB Peric		Requirements
		Draft For Working Team Only
		Aug 10 th Update
Technology	Demonstrations	<ul style="list-style-type: none">Critical Structure Targets: Veins, Arteries, Bile DuctMulti-Target: AV, BA, Sensitivity > 80%, Specificity > 80%, AUC > 80%, PrecisionMetrics: Sensitivity > 80%, Specificity > 80%, AUC > 80%, PrecisionObservation: 0-5 min natural observationsWorking Distance: 50 mmDepth: 50° (perpendicular to tissue)Video reviews: of all videos (scale 1 to 5 stars, Characteristics: detection, 3rd party - C3 80% above or equal to 4)
	Characteristics	<ul style="list-style-type: none">Multi-Target: AV, BA, BV, PPV, PPVMetrics: NPV, PPV in relation to prevalenceObservation: > 10 min natural observationsWorking Distance: 50 mm, 120mmDepth: 30° - 45° (angled to tissue)Video Reviews: The table aims explore impact of sensitivity adjustmentsScore Movement: VAB detection with both handheld (static) and robotic movement
	Notes	<ul style="list-style-type: none">Detection Dashboard: Results to be presented stratified per critical structure, multi-target combination, procedure, observation level, target dimension and ELB vs. ELB/s/7Statistical Analysis: Characterize ability and tradeoffs for higher sensitivity or specificity
	Biostatistics	<ul style="list-style-type: none">Data to be presented in a statistical manner across full data set (fixed Default Settings) and consulted with Ethicon BiostatisticianStatistical analysis to be run on all collected data sets except where data must be excluded (Data Exclusion to be aligned on jointly)Peer based analysis
	Technology	<ul style="list-style-type: none">Near real-time demonstration in Run Prep & Run Labs with detection and overlay (demonstrate more robust real time means, not to disrupt surgeon perception)Must allow user to operate under Real light (or white light) while also detecting the critical structure using the Eric technologyCritical structure detection recipes/algorithm must be mutually independent and not overlap with one another or with perfusionDetection recipes/algorithm must be specific to features of structures not individual scenes (e.g., Artery detection, Vein detection, Bile Duct Detection)No target labeling based calibration allowed, should be built into algorithmAllowed to auto expose calibration between targets/locations/scenesMax 30 Ws but CS: Characterize ability and tradeoffs to minimize wavelength as a function of performanceDeep learning algorithm review and analysis (exclusion, criteria, sensor label, criteria, temporal performance under static view, salience, etc.)
Program	Preclinical Model	<ul style="list-style-type: none">Animal Model: Porcine model LAR and Chole relevant scenes as best demonstrated in animal modelCritical Structure Targets: Veins, Arteries, Bile DuctProcedural Workflows: Cholecystectomy and Lower Anterior Resection (LAR)Observations: Natural observations focused and measured via ultrasound in porcine model (no CAFSC)Multi-Targets: Artery and Vein, Bile Duct and ArteryDetections work in near real-timeScope Working Distance: Demonstrate 50mm and 120mmScope Working Angles: Demonstrate 30° Characterize 85°Scope Movement: Characterize handheld motion and robotic scope movement
	Lap Characteristics	<ul style="list-style-type: none">Internal Feedback and External VOC Goals:Receive feedback on ability to detect and differentiate between veins, arteries and bile ductReceive feedback on ability to aid in LAR procedural workflow by helping surgeons identify arteries specifically the SMA and aorta, the vein specifically the IMA and Aorta junctionReceive feedback on ability to aid in Chole procedural workflow by helping surgeons identify the artery specifically the cystic artery, and bile duct. Including the biliary tree: cystic, hepatic, common bile duct.Both LAR and Chole clinical scenes are to demonstrate/characterized at full observation, partial observation.Receive feedback on technical assessment of Eric Technology
VOC		<ul style="list-style-type: none">Internal Feedback Participants: 2 Internal surgeons to review protocol and provide feedback in the Run Prep LabExternal VOC Participants: 10 Internal Colorectal and General surgeons who actively perform colorectal resections and cholecystectomies either laparoscopically or robotically.

“What I want to avoid, Tarik, is a scenario where ChemImage delivers the milestone, in ChemImage’s view, clearly documented that ChemImage recommends delivery of the milestone, and then there is this period of time in which ChemImage waits for the shoe to drop. And there is a declaration that, no, because the algorithms are not valid. And we then enter into a dispute, and then we go to arbitration. And then, you know, there’s an outcome. So, this one to me is about, why would we go forward with an invalid algorithm? Nobody wants that. You don’t want it, we don’t want it.”

Weekly Erie PM Meeting – August 11, 2022 (PX-1063) at 30:49-31:30

The Parties Understood That a JSC Deadlock on a Milestone Determination Would Lead to Arbitration



Tamara Lanier

*Director, Sales Excellence and
Enablement, Ethicon &
Project Erie JSC Member*

“In the event the JSC reaches an impasse, the Agreement directs the parties to arbitrate any resulting dispute.”

Lanier Aff. (PX-1018) ¶ 59 (citing DX 1 (Agreement § 12.9))

Section 2.4.3(a):

The Party With “Final Decision-Making Authority” Could Resolve a JSC Deadlock



Definitive Agreement (PX-1)

2.4.3 Voting and Deadlocks. The CI members shall collectively have one (1) vote on the JSC, and the Company members shall collectively have one (1) vote on the JSC. Decisions of the JSC shall be made by unanimous vote.

(a) In the event a deadlock occurs involving a matter that does not require modification of the Development Plan, the JSC shall attempt to resolve such deadlock for a period of thirty (30) days by engaging in good faith discussions. If such deadlock is not resolved after such thirty (30) day period, then each Party shall have the final decision-making authority with respect to the conduct of specific activities allocated to it under the Development Plan.

(b) In the event a deadlock occurs with respect to a modification of the Development Plan, the JSC shall attempt to resolve such deadlock for a period of thirty (30) days by engaging in good faith discussions. In the case of a JSC deadlock after such period, the issue will be escalated to the Head of Digital Surgery of Company and to the Chief Executive Officer of CI for resolution for a period of fifteen (15) days. If the issue cannot be resolved after such combined forty-five (45) day period, either Party may refer the unresolved matter for binding arbitration pursuant to Section 12.9 of this Agreement.

ChemImage Had “Final Decision-Making Authority” Over Feasibility on M1B



**Tamara
Lanier**

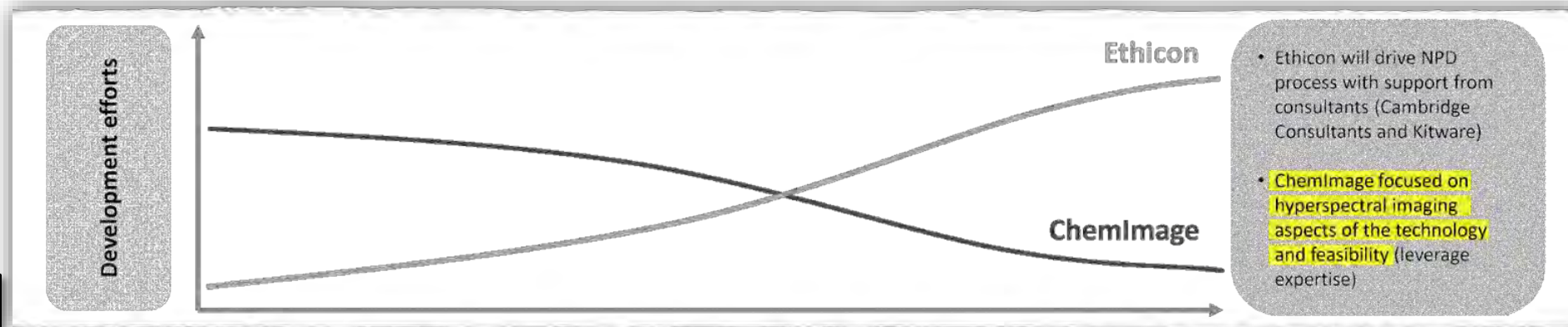
*Director, Sales Excellence and
Enablement, Ethicon &
Project Erie JSC Member*

“ ... the Agreement is structured such that ChemImage bears responsibility for technical development, and Ethicon bears responsibility for funding that development work and for commercializing the resulting product ...”

Lanier Aff. (PX-1018) ¶ 38

A. “ ... ChemImage was responsible for feasibility.”

Tr. 558:7(Lanier)



PX-408 at 9

Q. ... Prior to a determination of feasibility, this chart seems to make it look like ChemImage does the bulk of the work and Ethicon relatively less. Is that what's presented here? And over time that switches, right?

A. ... the ChemImage team is responsible for the feasibility work and taking the lead on that. ...

Tr. 558:14-22 (Lanier)

Whether Termination Was Inevitable Does Not Excuse Ethicon's Breach

- ▶ ***"When a contract's terms include a procedure for termination, here applicable New York law demands strict compliance with that procedure."***

Gen. Supply & Constr. Co. v. Goelet, 148 N.E. 778, 779 (N.Y. 1925) (Lehman, J.)

- ▶ ***"Even when one party to a contract is in breach, the other party's failure to comply with the contract's notice of termination provisions is itself an actionable breach of contract."***

Brueckner v. You Can Beam LLC, 2021 WL 2158733, at *4 (S.D.N.Y. May 27, 2021) (Rakoff, J.) (emphasis added)

- ▶ "Sonomed committed a material breach by terminating the Agreement ... in contravention of [the contract's] notice period" even if Bausch & Lomb improperly manufactured Sonomed's products.

Bausch & Lomb Inc. v. Bressler, 977 F.2d 720, 726-27 (2d Cir. 1992)

Whether Termination Was Inevitable Does Not Excuse Ethicon's Breach

- ▶ "Celgene is likely to succeed in showing that Nimbus's August 13 letter did not terminate the Warrant. ***Nimbus cannot evade the 30-day notice-and-opportunity-to-cure requirement by invoking the general doctrine of futility.*** Under New York law, a terminating party's failure to afford contractually-required notice and cure is excusable as futile only in limited circumstances. Among these are where the non-performing party (1) expressly repudiates the parties' contract or (2) abandons performance thereunder. Celgene never repudiated the Warrant."

Nimbus Therapeutics, LLC v. Celgene Corp., 570 F. Supp. 3d 100, 116 (S.D.N.Y. 2021) (Rakoff, J.) (emphasis added) (cleaned up)

- ▶ "New York law is also clear that freedom of contract prevails in an arm's length transaction between sophisticated parties such as these, and in the absence of countervailing public policy concerns there is no reason to relieve them of the consequences of their bargain."

Id. at 117 (cleaned up)

Roadmap of the Presentation

- I.** JSC Milestone Determination
- II.** Scope of the Termination Letter
- III.** Ethicon Failed to Prove Breach
- IV.** Linkage Scenarios
- V.** Tortious Interference
- VI.** IP Impairment Damages

**Ethicon Cannot Now Assert a Basis for
Termination That Was Not Asserted In Its
March 6, 2023 Termination Letter.**

Black Letter Law: Ethicon Is Limited to Its Termination Letter

- ▶ “Where a contract provides that ***a party must fulfill specific conditions*** ***before terminating for cause***, “those conditions are enforced as written and ***the party must comply with them.***”

O’Brien & Gere, Inc. of N. Am. v. G.M. McCrossin, Inc., 184 A.D.3d 1804, 1805-06 (4th Dep’t 2017);

- ▶ “[W]ritten notice [and cure] requirements are fully enforceable” under New York law, and their consequence is that “***where no notice was given ... there can be no breach***,” because the allegedly breaching party “was not afforded the opportunity to cure.”

USI Ins. Servs. LLC v. Miner, 801 F. Supp. 2d 175, 181 (S.D.N.Y. 2011) (Preska, J.)

Black Letter Law: Ethicon Is Limited to Its Termination Letter

- ▶ “[C]ontractually-required **notices** of breach **must provide sufficient information** for the noticed party **to determine what steps were necessary to cure** the alleged breaches.”

In re 4Kids Ent., Inc., 463 B.R. 610, 682 (Bankr. S.D.N.Y. 2011)

- ▶ “[Defendants] cannot rely on alleged breaches not included in its Termination Letter to support its attempt to terminate the [Agreement] [Defendant] alleged **additional breaches not mentioned in the Termination Letter**, but the Court finds such breaches cannot support termination because the evidence at trial did not show [Defendant] gave [Plaintiff] written notice of such alleged breaches.”

In re Ingenu, Inc., 2024 WL 3634243, (Bankr. S.D. Cal. Feb. 13, 2024)

Ethicon Cannot Invent New Bases For ChemImage's Purported Breach

ETHICON

PART OF THE ~~Johnson & Johnson~~ FAMILY OF COMPANIES
Ethicon, Inc.
a Johnson & Johnson company
U.S. Route 22 West
Somerville, NJ 08876

March 6, 2023

ChemImage Corporation
7325 Penn Avenue, Suite 200
Pittsburgh, PA 15208

ATTN: Matthew Nelson, Chief Technology Officer, and Chief Operating Officer

Re: RESEARCH, DEVELOPMENT, LICENSE AND COMMERCIALIZATION AGREEMENT

Dear Matthew and Chief Operating Officer:

Pursuant to Section 10.3.2(a) of the Research, Development, License and Commercialization Agreement between Ethicon, Inc. ("Ethicon") and ChemImage Corporation ("CI") effective as of December 27, 2019 (the "Agreement"), Ethicon is hereby providing notice to CI via this letter of its intent to terminate the Agreement for cause for failure to achieve a Development Milestone, which constitutes a Material Breach. In particular, a final report provided on December 16, 2022, for a subset of the critical structures, veins, arteries, and bile ducts (collectively, "VAB") that are a part of Milestone 1B in the Agreement, is not evaluable. In fact, several errors and flaws in collecting and processing data were identified upon review of the final report. Specifically, uncertainty with respect to negative controls, use of omnipresent ignore labels, and data discrepancies between a preliminary report and the final report, amongst others have been identified. With respect to ignore labels, the process of using such labels was done contrary to the process proposed and agreed upon in data review board meetings and without review by Ethicon. Further, pursuant to the Agreement, Ethicon had a third party review the final report and underlying data examples provided and the third party concluded that as a direct result of the implementation of ignore labels, there is a significant risk that the metrics are misleading indicators of performance and that the final report cannot be evaluated on the basis of these metrics.

Ethicon previously communicated its concerns with the collecting and data processing practices used by CI for Milestone 1A in JSC Meeting 10 which was documented in writing by the parties in the JSC Meeting 10 Minutes, on October 30, 2020. In that meeting and as documented in those minutes, Ethicon emphasized that such practices needed to be addressed for Milestone 1B; however, as outlined, errors due to such practices still exist in the final report for VAB. These errors are systematic and cannot be remedied by simply re-running the data and re-generating another report; rather, previously completed labs, data collection, and annotation processes would need to be reworked and repeated. Additionally, on June 20, 2022, Ethicon and CI met during which Ethicon indicated to CI that the program would be at high risk of cancellation if the program

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CONFIDENTIAL

PX-3

DEF_0072278
Page 2 of 3

[1] "uncertainty with respect to negative controls,"

[2] "use of omnipresent ignore labels,"

[3] "data discrepancies between a preliminary report and the final report"

Pursuant to Section 10.3.2(a) of the Research, Development, License and Commercialization Agreement between Ethicon, Inc. ("Ethicon") and ChemImage Corporation ("CI") effective as of December 27, 2019 (the "Agreement"), Ethicon is hereby providing notice to CI via this letter of its intent to terminate the Agreement for cause for failure to achieve a Development Milestone, which constitutes a Material Breach. In particular, a final report provided on December 16, 2022, for a subset of the critical structures, veins, arteries, and bile ducts (collectively, "VAB") that are a part of Milestone 1B in the Agreement, is not evaluable. In fact, several errors and flaws in collecting and processing data were identified upon review of the final report. Specifically, uncertainty with respect to negative controls, use of omnipresent ignore labels, and data discrepancies between a preliminary report and the final report, amongst others have been identified. With respect to ignore labels, the process of using such labels was done contrary to the process proposed and agreed upon in data review board meetings and without review by Ethicon. Further, pursuant to the Agreement, Ethicon had a third party review the final report and underlying data examples provided and the third party concluded that as a direct result of the implementation of ignore labels, there is a significant risk that the metrics are misleading indicators of performance and that the final report cannot be evaluated on the basis of these metrics.

3/6/23 Termination Letter (PX-3)

PX-3 at 2

Ethicon Now Claims That ChemImage Was Required to Independently Meet the Performance Metrics for Chole & LAR



Dr. Steen Hansen

*Director, Advanced
Visualization Technologies,
Ethicon & Ethicon's Project
Erie Technical Lead*

- Q. And what was your understanding of what ChemImage was required to demonstrate in order to pass the VAB portion of milestone 1B?
- A. **Well, in continuation of the underlying agreement, it needed to be in a clinically relevant procedure within laparoscopies. So that's called an LAR and cholecystectomy, which are both abdominal procedures. And then it needed to be demonstrated within those sensitivity and specificity at 80 percent, and importantly up to 5 millimeters of obscuration, and by that means in a stratified manner ...**

Tr. 727:20-728:6 (Hansen)

The Parties Never Agreed to Evaluate Chole & LAR Data in Isolation



Erie Program CS M1B VAB Acceptance Protocol Reflecting VAB Performance Requirements (2-Dec-2022)	
Technology	Detection Performance Metrics <ul style="list-style-type: none">Demonstrate:<ul style="list-style-type: none"><u>Critical Structure Targets:</u> Veins, Arteries, Bile Duct + Mean of Sensitivity, Mean of Specificity, Mean of AUC $\geq 80\%$ AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity<u>Multi-Target:</u> Mean of Sensitivity, Mean of specificity, Mean of AUC $\geq 80\%$ AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity<u>Obscuration:</u> 0 – 5 mm natural<u>Working Distance:</u> VA: 50 mm; B: 80 mm<u>Angle:</u> 0° (Normal Incidence)Characterize<ul style="list-style-type: none"><u>Multi-Target:</u> Arteries + Veins, Bile Duct + Artery<u>Metrics:</u> IOU, In relation to prevalence<u>Obscuration:</u> > 5 – 10 mm natural obscurations<u>Working Distance:</u> VA: 80 mm<u>Angle:</u> $\pm 30^\circ$<u>Video reviews:</u> of Representative Videos (Clinical Evaluation Scale 1 to 5 vote, ChemImage, Ethicon, 3rd party - CC)<u>Scope Movement:</u> VAB detection with handheld trocar (port constrained) & robotic movement<u>Negative Control Scenes:</u> Show additional 10% (of total demonstrated N) to detection scenes (e.g., Bile Duct in Neck scene)Notes:<ul style="list-style-type: none"><u>Detection Dashboard:</u> Results to be presented stratified per critical structure, multi-target combination, procedure, obscuration level, target diameter > 1mm and EL8 vs. EL5/6/7.Characterize ability and tradeoffs for higher sensitivity or specificity
	Biostatistics <ul style="list-style-type: none">Data to be presented in a statistical manner across full data set (Documented & Consistent Case Configuration Settings) and consulted with Ethicon BiostatisticianStatistical analysis to be run on all collected data sets except where data must be excluded (Data Exclusion and Inclusion to be aligned on jointly)
Technology	<ul style="list-style-type: none">Pixel based analysisPost-processed statistical summaryScoring and all reported metrics must be based on the real-time embedded pipeline with no additional processing of the embedded results outside of sensitivity setting optimization evaluationNear real-time (min 2fps) demonstration in Run Lab & Surgeon VOC with detection and overlay. Characterize ability and tradeoffs to achieve real-time (≥ 10 fps)Must allow user to operate under RGB light (or white light) while also detecting the critical structures using the Erie technologyVAB detection recipes must be mutually independent and not overlap with perfusionDetection recipes/algorithms must be specific to families of structures not individual scenes i.e., Artery detection, Vein detection, Bile Duct DetectionNo target labeling-based calibration allowed, should be built into algorithmsAllowed to auto expose calibration between targets/locations/scenesAllowed to adjust Sensitivity Control prior to Near Real-Time demonstrationsMax 10 W/Ls but ≤ 5 an Objective (Nice to Have) Requirement. Characterize ability and tradeoffs to minimize wavelengths as a function of performanceDeep learning algorithm review and analysis (exclusion criteria, ignore label criteria, temporal persistence, saliency maps or intelligible AI prior to 15 Jan 2023)
Program	Preclinical Model <ul style="list-style-type: none">Animal Model: Porcine model LAR and Chole relevant scenes as best demonstrated in animal model.Critical Structure Targets: Veins; Arteries; Bile DuctProcedural Workflows: Cholecystectomy and Lower Anterior Resection (LAR)Multi-Targets: Arteries + Veins; Bile Duct + ArteryObscurements: Natural obscurations found and measured via ultrasound in porcine model (no CAFCO)
	Lap Characteristics <ul style="list-style-type: none">Scope Working Distance: Demonstrate 50 mm for VA, 80 mm for B; Characterize 80 mm for VAScope Working Angles: Demonstrate 0°, Characterize $\pm 30^\circ$Scope Movement: Characterize handheld trocar and robotic scope movement
	Internal Feedback & External VOC <p>Internal Feedback and External VOC Goals:</p> <ul style="list-style-type: none">Receive feedback on ability to detect and differentiate between Veins, Arteries and Bile duct.Receive feedback on ability to aid in LAR procedural workflow by helping surgeons identify arteries specifically the IMA and IMA/Aorta junction, and the IMV specificallyReceive feedback on ability to aid in Chole procedural workflow by helping surgeons identify the artery specifically the cystic artery, and bile duct. Including the biliary tree: cystic, hepatic, common bile duct.Both LAR and Chole clinical scenes are to be demonstrated/characterized at full obscuration.Receive feedback on technical assessment of Erie Technology <p>Internal Feedback Participants: 2 CI surgeons, Ethicon JSC Members + invited Ethicon Leadership observe detections and provide feedback in EL8 at VIP Leadership demo</p> <p>External VOC Participants: Up to 8 external: Colorectal (4) and General surgeons (4) who actively perform colorectal resections and cholecystectomies either laparoscopically or robotically.</p>
	Reviews: <ul style="list-style-type: none">VOC FeedbackJSC ReviewInternal Ethicon Working and Leadership ReviewExternal 3rd Party Review

ChemImage Only Needed to Meet the Demonstrate Metrics for All Collected Data



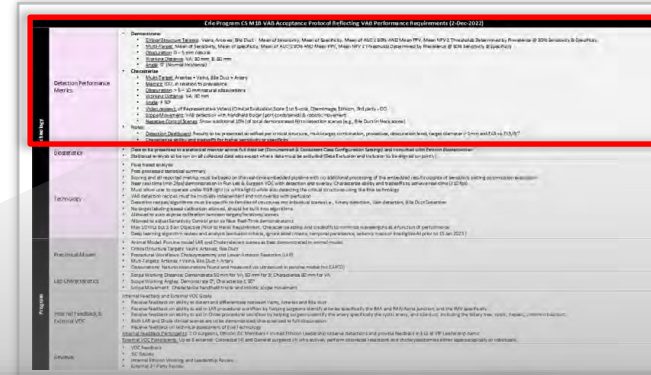
Erie Program CS M1B VAB Acceptance Protocol Reflecting VAB Performance Requirements (2-Dec-2022)	
Performance	<ul style="list-style-type: none"> • Critical Structure Targets: Veins, Arteries, Bile Duct - Mean of Sensitivity, Mean of Specificity, Mean of AUC \geq 80% AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity • Multi-Target: Mean of Sensitivity, Mean of specificity, Mean of AUC \geq 80% AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity • Obscuration: 0 – 5 mm natural • Working Distance: VA: 50 mm; B: 80 mm • Angle: 0° (Normal Incidence)
Detection/Performance Metrics	<ul style="list-style-type: none"> • Critical Structure Targets: Veins, Arteries, Bile Duct - Mean of Sensitivity, Mean of Specificity, Mean of AUC \geq 80% AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity • Multi-Target: Mean of Sensitivity, Mean of specificity, Mean of AUC \geq 80% AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity • Obscuration: 0 – 5 mm natural • Working Distance: VA: 50 mm; B: 80 mm • Angle: 0° (Normal Incidence)
Obscuration	<ul style="list-style-type: none"> • Critical Structure Targets: Veins, Arteries, Bile Duct - Mean of Sensitivity, Mean of Specificity, Mean of AUC \geq 80% AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity • Multi-Target: Mean of Sensitivity, Mean of specificity, Mean of AUC \geq 80% AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity • Obscuration: 0 – 5 mm natural • Working Distance: VA: 50 mm; B: 80 mm • Angle: 0° (Normal Incidence)
Working Distance	<ul style="list-style-type: none"> • Critical Structure Targets: Veins, Arteries, Bile Duct - Mean of Sensitivity, Mean of Specificity, Mean of AUC \geq 80% AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity • Multi-Target: Mean of Sensitivity, Mean of specificity, Mean of AUC \geq 80% AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity • Obscuration: 0 – 5 mm natural • Working Distance: VA: 50 mm; B: 80 mm • Angle: 0° (Normal Incidence)
Angle	<ul style="list-style-type: none"> • Critical Structure Targets: Veins, Arteries, Bile Duct - Mean of Sensitivity, Mean of Specificity, Mean of AUC \geq 80% AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity • Multi-Target: Mean of Sensitivity, Mean of specificity, Mean of AUC \geq 80% AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity • Obscuration: 0 – 5 mm natural • Working Distance: VA: 50 mm; B: 80 mm • Angle: 0° (Normal Incidence)

Erie Program CS M1B VAB Acceptance Protocol Reflecting VAB Performance Requirements (2-Dec-2022)

Detection Performance Metrics

- **Demonstrate:**
 - Critical Structure Targets: Veins, Arteries, Bile Duct - Mean of Sensitivity, Mean of Specificity, Mean of AUC \geq 80% AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity
 - Multi-Target: Mean of Sensitivity, Mean of specificity, Mean of AUC \geq 80% AND Mean PPV, Mean NPV \geq Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity
 - Obscuration: 0 – 5 mm natural
 - Working Distance: VA: 50 mm; B: 80 mm
 - Angle: 0° (Normal Incidence)

ChemImage Only Needed to Characterize Data Without Meeting Specified Metrics



Erie Program CS M1B VAB Acceptance Protocol Reflecting VAB Performance Requirements (2-Dec-2022)

Detection Performance Metrics

- **Characterize**
 - Multi-Target: Arteries + Veins, Bile Duct + Artery
 - Metrics: IOU, in relation to prevalence
 - Obscuration: > 5 – 10 mm natural obscurations
 - Working Distance: VA: 80 mm
 - Angle: $\pm 30^\circ$
 - Video reviews: of Representative Videos (Clinical Evaluation Scale 1 to 5 vote, ChemImage, Ethicon, 3rd party - CC)
 - Scope Movement: VAB detection with handheld trocar (port constrained) & robotic movement
 - Negative Control Scenes: Show additional 10% (of total demonstrated N) to detection scenes (e.g., Bile Duct in Neck scene)

40

The Inclusion and Exclusion Criteria Were Unchanged From the VAB Q3 Interim Report

CS VAB Q3 Interim Report Acceptance Protocol Inclusion Criteria

- All CS M1B VAB collected run files for purpose of Milestone demonstration during EL5-EL8 not excluded by Exclusion Criteria that satisfy Consistent Case Configuration
- Obscured and unobscured CS Targets (VAB)
- Standard working distances:
 - Vein, Artery: 50 mm
 - Bile Duct: 80 mm

PX-780 at 24

9/30/22 VAB Q3 Interim Report (PX-780)

CS VAB Q3 Interim Report Acceptance Protocol Exclusion Criteria

No.	Exclusion Category	Criteria for Exclusion
1	Saturation	<ul style="list-style-type: none">• > 15 x 15 pixel saturation area directly on a target• > 30 x 30 pixel saturation area in the background• Does not include glare unless glare covers more than 50% of the target
2	Low Signal	<ul style="list-style-type: none">• Less than 30 counts on average in center of image
3	Excessive Motion / Poor Image Alignment	<ul style="list-style-type: none">• Motion compensated images are > 10 pixel out of alignment in the x and/or y direction
4	Obscured or Bad Fields of View	<ul style="list-style-type: none">• Tools or other surgical implements block more than 50% of the FOV• Dirty or foggy endoscope camera• Large pools of blood
5	Software and Hardware Bugs	<ul style="list-style-type: none">• Banding or mixed laser frames• Missing image frames• Laser not firing• Other odd behaviors
6	Operator Error	<ul style="list-style-type: none">• Examples:<ul style="list-style-type: none">• Collect runfile with storz light on• Collect runfiles with wrong settings• Collect runfile before FOV is prepped by surgeon
7	Low confidence ground truth	<ul style="list-style-type: none">• Confidence ranking of 2 or lower
8	Duplicate run files of the same scene	<ul style="list-style-type: none">• Redundant & Do not contribute to Statistical Manner evaluation
9	Excursion data not otherwise included	<ul style="list-style-type: none">• Examples: MIS, gallstones, carcass, autogain excursion, gradient study, ICG run files, mapping, methylene blue study, use of stent, intended motion, working distance excursions

PX-780 at 23

If Ethicon Wanted Different Performance Metrics, They Should Have Negotiated Before the Acceptance Protocol Was Finalized



9/30/22 VAB Q3 Interim Report (PX-780)

CS VAB Q3 Interim Report Summary & Impact on Critical Structures

- Q3 VAB Interim Report Summary & Next Steps
 - VAB Interim results suggest path to M1B VAB milestone acceptance based on demonstrate data performance meeting criteria defined in current acceptance protocol
 - Characterize data presented as defined in acceptance protocol
 - Preferred configuration currently recommended to be E2 configuration
 - Final Decision will be confirmed following EL 7.5
- Path to CS M1B VAB Final Report
 - Proceed to EL 7.5 to prepare for successful VOC practice in EL 8 and demonstration at EL 9
 - Final report will follow similar approach to interim report in terms of content structure and level of detail
 - Updates from EL 7.5, 8 & 9 will be included as needed
 - Inputs from video evaluations will be incorporated into final report
- Impact on Nerve and Ureter
 - Priority in Q2, Q3 & Q4 shifted to VAB resulting in nerve and ureter data collection occurring infrequently or when present in VAB scenes
 - Focus of algorithm and recipe refinement was VAB targets
 - Frequency of nerve and ureter collections can increase in 2023 studies if consistent with goals of Erie program

PX-780 at 103

On Dec. 2, 2022, the VAB Acceptance Protocol Is Finalized After Months of Negotiation

VAB Final Report Acceptance Protocol *Inclusion* and *Exclusion* Criteria Do Not Limit Data to Chole and LAR

- All CS M1B VAB collected run files for purpose of Milestone demonstration during EL5-EL8 not excluded by Exclusion Criteria that satisfy Consistent Case Configuration
- Obscured and unobscured CS Targets (VAB)

CS VAB Final Report

Acceptance Protocol *Inclusion* Criteria

- All CS M1B VAB collected run files for purpose of Milestone demonstration during EL5-EL8 not excluded by Exclusion Criteria that satisfy Consistent Case Configuration
- Obscured and unobscured CS Targets (VAB)
- Standard working distances:
 - Vein, Artery: 50 mm
 - Bile Duct: 80 mm

Shona Stewart (sstewart@chemimage.com)
Aaron Smith (smitha@chemimage.com)
Alyssa Zrimsek (zrimseka@chemimage.com)
Sidney Coombs (coombss@chemimage.com)
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PX-768 at 31

CS VAB Final Report

Acceptance Protocol *Exclusion* Criteria

No.	Exclusion Category	Criteria for Exclusion	N in EL5-EL7.5, EL8 Lab 1&2
1	Saturation	<ul style="list-style-type: none">> 15 x 15 pixel saturation area directly on a target> 30 x 30 pixel saturation area in the backgroundDoes not include glare unless glare covers more than 50% of the target	143 files (16%)
2	Low Signal	<ul style="list-style-type: none">Less than 30 counts on average in center of image	1 file (<1%)
3	Excessive Motion / Poor Image Alignment	<ul style="list-style-type: none">Motion compensated images are > 10 pixel out of alignment in the x and/or y direction	NA
4	Obscured or Bad Fields of View	<ul style="list-style-type: none">Tools or other surgical implements block more than 50% of the FOVDirty or foggy endoscope cameraLarge pools of blood	9 files (1%) FOV not aligned before collection or better FOV acquired in subsequent re-acquisition
5	Software and Hardware Bugs	<ul style="list-style-type: none">Banding or mixed laser framesMissing image framesLaser not firingOther odd behaviors	NA
6	Operator Error	<ul style="list-style-type: none">Examples:<ul style="list-style-type: none">Collect runfile with Storz light onCollect runfiles with wrong settings	1 file (<1%)
7	Low confidence ground truth	<ul style="list-style-type: none">Confidence ranking of 2 or lower	15 files (2%) 2 FOVs in EL5: Urt w/ GT score 2, Ilio Nerve w/ GT score 2 11 gastropiploic artery files in EL7.5 with unresolvable GT
8	Duplicate run files of the same scene	<ul style="list-style-type: none">Redundant & Do not contribute to Statistical Manner evaluation	97 files (11%)
9	Excursion data not otherwise included	<ul style="list-style-type: none">Examples: MIS, gallstones, carcass, autogain excursion, gradient study, ICG run files, mapping, methylene blue study, use of stent, intended motion, working distance excursions	Excursions (gallstone, carcass, working distance, methylene blue, PLL) = 41 files (5%) Motion/Angle (may be included in Characterize) = 106 files (12%)

Note: Files may fall into multiple categories (example: motion file + non-evaluable due to saturation)

Updated 11/21/22

PX-768 at 30

The Parties Agreed on What the Acceptance Protocol's Detection Requirements Meant



Dr. Patrick Treado

*Founder & President,
ChemImage
& JSC Member, Project Erie*

Q. Okay. Were [the 80 percent thresholds in the heading Detection Performance Metrics, under the subheading Demonstrate] required to be shown for specific potential surgical procedures such as an LAR or I think it's CYC, cholecystectomy?

A. **No.**

Tr. 133:17-20 (Treado)



Tamara Lanier

*Director, Sales Excellence and
Enablement, Ethicon &
Project Erie JSC Member*

Q. You've never taken the position that ChemImage failed to satisfy the metrics for Milestone 1B because they didn't show 80 percent for those two specific procedures, true?

A. **Correct. We took a different position.**

Tr. 573:16-573:19 (Lanier)

Dr. Hansen Admits That Ethicon Never Claimed That ChemImage Failed Because It Did Not Show 80% for LAR & Chole Data Only



Dr. Steen Hansen

*Director, Advanced
Visualization Technologies,
Ethicon & Ethicon's Project
Erie Technical Lead*

Q. Does it say, for example, that it didn't achieve 80 percent sensitivity or 80 percent specificity?

A. No.

Q. Am I right, sir, that there's no study or analysis or data that Ethicon ever delivered to ChemImage showing that the Project Erie study failed to meet these performance criteria at an 80 percent level for sensitivity or specificity?

A. No.

Q. No, meaning that no such report was ever delivered, true?

A. In terms of the 80/80?

Q. Yes.

A. No.

Tr. 749:1-12 (Hansen)

Ethicon Never Claimed That ChemImage Breached for Failing to Show Chole & LAR Data

CS VAB Final Report

Detection Performance: Clinical Procedures – EL5 – EL8

Structure	Target	Obscuration	E1					E2				
			Sens	Spec	PPV	NPV	N	Sens	Spec	PPV	NPV	N
Cholecystectomy	Cystic Artery	0 (Unobscured)	99.6± 0.9	88.2± 6.2	14.1± 9.8	100.0± 0.0	16	99.5± 1.3	87.0± 4.3	13.4±10.0	100.0± 0.0	12
		>0 – 1	91.9	92.8	26.0	99.8	1	91.9	92.6	23.7	99.8	1
		>1 – 2.5	95.1± 5.0	90.1± 1.0	17.0± 8.2	99.9± 0.1	6	92.5±14.2	90.3± 3.7	19.0±13.1	99.5± 1.1	7
		>2.5 – 5	99.9± 0.3	89.6± 4.6	12.8±12.1	100.0± 0.0	6	100.0± 0.0	88.4± 4.2	10.8±13.5	100.0± 0.0	2
		>5 -7.5	-	-	-	-	0	-	-	-	-	0
		>7.5 – 10	-	-	-	-	0	-	-	-	-	0
	Bile Duct	0 (Unobscured)	94.1±11.1	86.8± 6.5	29.8±20.8	99.6± 0.6	14	97.2± 5.8	86.6± 6.8	37.3±19.3	99.7± 0.6	13
		>0 – 1	-	-	-	-	0	-	-	-	-	0
		>1 – 2.5	92.6± 6.3	91.8± 4.1	72.4±12.0	98.1± 1.3	10	90.4± 8.7	92.0± 4.9	73.1±14.7	97.7± 1.7	8
		>2.5 – 5	90.5± 9.1	97.1± 2.7	86.2±13.8	97.3± 3.8	6	87.2±15.7	91.0± 5.0	68.8±10.3	96.7± 4.6	7
		>5 -7.5	-	-	-	-	0	-	-	-	-	0
		>7.5 – 10	-	-	-	-	0	-	-	-	-	0
LAR	Artery	0 (Unobscured)	83.7±30.0	82.9±10.9	31.3±20.4	96.0± 7.8	15	88.1±14.2	86.2±10.6	41.9±11.0	98.2± 2.4	10
		>0 – 1	80.0±31.5	89.5± 4.6	44.7±14.4	95.8± 7.1	3	67.7±55.8	90.8± 5.3	22.4±17.9	95.8± 7.2	3
		>1 – 2.5	65.3±27.9	90.3± 4.3	45.4±22.2	92.7± 7.1	8	73.5±25.6	91.7± 6.7	44.6±26.1	97.5± 3.7	8
		>2.5 – 5	99.9	64.3	15.5	100.0	1	86.7	91.6	46.7	98.8	1
		>5 -7.5	-	-	-	-	0	-	-	-	-	0
		>7.5 – 10	-	-	-	-	0	-	-	-	-	0
	Vein	0 (Unobscured)	84.8±25.8	89.0± 5.7	22.0±10.2	99.3± 1.5	12	85.4±28.3	92.8± 4.0	30.0±15.4	99.3± 1.3	8
		>0 – 1	53.1±34.7	95.9± 2.3	54.1±19.8	93.3± 6.3	4	62.6±40.5	95.7± 2.5	46.0±18.2	94.6± 6.4	6
		>1 – 2.5	77.5±32.5	89.3± 8.4	43.0±18.4	95.4± 9.0	5	88.1±26.1	92.4± 5.5	48.3±24.3	97.1± 6.5	5
		>2.5 – 5	19.2	85.4	17.6	86.7	1	83.9	82.5	18.3	99.1	1
		>5 -7.5	-	-	-	-	0	-	-	-	-	0
		>7.5 – 10	-	-	-	-	0	-	-	-	-	0

Ethicon Knew the Chole & LAR Sample Sizes Before the Final Report Was Submitted

VAB Q3 Interim Report

Procedure	Structure				E1	E2
			Sens	Spec	N	N
Cholecystectomy	Cystic Artery	1 st	99.9 ± 0.0	85.4 ± 5.1	7	5
		2 nd	99.9 ± 0.0	91.2 ± 3.3	5	2
		3 rd	-	-	0	0
	Bile Duct	1 st	88.1 ± 11.7	90.6 ± 5.6	4	6
		2 nd	92.1 ± 5.8	95.0 ± 4.4	8	5
		3 rd	-	-	0	0
LAR	Artery	1 st	80.8 ± 31.1	87.1 ± 6.8	5	4
		2 nd	86.1 ± 12.9	93.8 ± 2.9	5	1
		3 rd	-	-	0	0
	Vein	1 st	89.8 ± 14.1	93.6 ± 5.1	5	4
		2 nd	90.2 ± 8.9	96.1 ± 1.3	5	2
		3 rd	-	-		

PX-780 at 15

Ethicon Knew and Was Involved in Project Erie's Data Collection

CS M1B EL8 VAB Run Study Test Plan At A Glance (1-Station For Wednesday Labs)

Lab No.	Lab Focus	Instrument Configurations	Vessel Targets	Nerve Targets	Bile Duct Targets	Ureter Targets	Notes & Excursions
1	VAB Verification	OH08A (Units 5 (E1) & 10 (E2))	9	4	1	0	
2	VAB Verification	OH08A (Units 5 (E1) & 10 (E2))	9	4	1	0	
3	VOC Practice	OH08A (Units 10 (E2) & 5 (E1))	3	0	1	0	• Single Station - Handheld
4	VOC Practice	OH08A (Units 12 (E2) & 5 (E1))	3	0	1	0	• Single Station – Robot
5	Cholecystectomy +LAR	OH08A (Units 10 (E2) & 12 (E2))	3	0	1	0	
6	Cholecystectomy +LAR + Internal Demo	OH08A (Units 10 (E2) & 12 (E2))	3	0	1	0	
Total			30	8	6	0	



Aaron Smith (smitha@chemimage.com)
Robert Draham (drahamr@chemimage.com)

PX-26 at 30

10/21/22 EL8 TRR (PX-26)

01-November-2022 (Day 2)

Open Procedure (Lab 1; Pig)- Verification

Laser Power Measurements

Right Neck Vessels obscured / Bile Duct (cystic, hepatic and common) (E5 OH08A/ E10 OH08A for both targets)

Right Neck Vessels unobscured / Bile Duct (cystic, hepatic and common) unobscured (E5 OH08A/ E10 OH08A for both targets)

Left Neck Vessels obscured/ Right Gastrosplenic vessels obscured (E5 OH08A/ E10 OH08A for both targets)

Left Neck Vessels unobscured/ Right Gastrosplenic vessels unobscured (E5 OH08A/ E10 OH08A for both targets)

Right renal vessels obscured / Right Forelimb vessels obscured (E5 OH08A/ E10 OH08A for both targets)

Right renal vessels unobscured / Right Forelimb vessels unobscured (E5 OH08A/ E10 OH08A for both targets)

Inferior mesenteric vessels obscured / Left Forelimb vessels obscured (E5 OH08A/ E10 OH08A for both targets)

Inferior mesenteric vessels obscured / Left Forelimb vessels unobscured (E5 OH08A/ E10 OH08A for both targets)

Left renal vessels obscured and unobscured (E5 OH08A/ E10 OH08A for both targets)

PX-26 at 32

By September 2022, Ethicon Knew How Much Chole and LAR Data ChemImage Had and How Much More It Could Collect

VAB Q3 Interim Report

Procedure	Structure		Sens		Spec	
Cholecystectomy	Cystic Artery	1 st	99.9 ± 0.0		85.4 ± 5.1	
		2 nd	99.9 ± 0.0		91.2 ± 3.3	
		3 rd	-		-	
	Bile Duct	1 st	88.1 ± 11.7		90.6 ± 5.6	
		2 nd	92.1 ± 5.8		95.0 ± 4.4	
		3 rd	-		-	
LAR	Artery	1 st	80.8 ± 31.1		87.1 ± 6.8	
		2 nd	86.1 ± 12.9		93.8 ± 2.9	
		3 rd	-		-	
	Vein	1 st	89.8 ± 14.1		93.6 ± 5.1	
		2 nd	90.2 ± 8.9		96.1 ± 1.3	
		3 rd	-		-	

E1	E2
N	N
7	5
5	2
0	0
4	6
8	5
0	0
5	4
5	1
0	0
5	4
5	2

PX-780 at 15

VAB Final Report

Structure	Target	Obscuration	E1	E2
Cholecystectomy	Cystic Artery	0 (Unobscured)	N	N
		>0 - 1	16	12
		>1 - 2.5	1	1
		>2.5 - 5	6	7
		>5 - 7.5	6	2
		>7.5 - 10	0	0
	Bile Duct	0 (Unobscured)	0	0
		>0 - 1	14	13
		>1 - 2.5	0	0
		>2.5 - 5	10	8
		>5 - 7.5	6	7
		>7.5 - 10	0	0
LAR	Artery	0 (Unobscured)	15	10
		>0 - 1	3	3
		>1 - 2.5	8	8
		>2.5 - 5	1	1
		>5 - 7.5	0	0
		>7.5 - 10	0	0
	Vein	0 (Unobscured)	12	8
		>0 - 1	4	6
		>1 - 2.5	5	5
		>2.5 - 5	1	1
		>5 - 7.5	0	0
		>7.5 - 10	0	0

PX-768 at 15

Roadmap of the Presentation

I. JSC Milestone Determination

II. Scope of the Termination Letter

III. Ethicon Failed to Prove Breach

IV. Linkage Scenarios

V. Tortious Interference

VI. IP Impairment Damages

**Ethicon's Ever-Changing Theories Fail to
Show That ChemImage Breached the
Agreement By Failing to Meet a Milestone.**

Ethicon Did Not Claim ChemImage Fell Below Milestone 1B Performance Metrics: It Claimed the VAB Report Was "Not Evaluable"

ETHICONPART OF THE ~~Johnson & Johnson~~ FAMILY OF COMPANIESEthicon, Inc.
a Johnson & Johnson company
U.S. Route 22 West
Somerville, NJ 08876

March 6, 2023

ChemImage Corporation
7325 Penn Avenue, Suite 200
Pittsburgh, PA 15208

ATTN: Matthew Nelson, Chief Technology Officer, and Chief Operating Officer

Re: RESEARCH, DEVELOPMENT, LICENSE AND COMMERCIALIZATION AGREEMENT

Dear Matthew and Chief Operating Officer:

Pursuant to Section 10.3.2(a) of the Research, Development, License and Commercialization Agreement between Ethicon, Inc. ("Ethicon") and ChemImage, Corporation ("CI") effective as of December 27, 2019 (the "Agreement"), Ethicon is hereby providing notice to CI via this letter of its intent to terminate the Agreement for cause for failure to achieve a Development Milestone, which constitutes a Material Breach. In particular, a final report provided on December 16, 2022, for a subset of the critical structures, veins, arteries, and bile ducts (collectively, "VAB") that are a part of Milestone 1B in the Agreement, is not evaluable. In fact, several errors and flaws in collecting and processing data were identified upon review of the final report. Specifically, uncertainty with respect to negative controls, use of omnipresent ignore labels, and data discrepancies between a preliminary report and the final report, amongst others have been identified. With respect to ignore labels, the process of using such labels was done contrary to the process proposed and agreed upon in data review board meetings and without review by Ethicon. Further, pursuant to the Agreement, Ethicon had a third party review the final report and underlying data examples provided and the third party concluded that as a direct result of the implementation of ignore labels, there is a significant risk that the metrics are misleading indicators of performance and that the final report cannot be evaluated on the basis of these metrics.

Ethicon previously communicated its concerns with the collecting and data processing practices used by CI for Milestone 1A in JSC Meeting 10 which was documented in writing by the parties in the JSC Meeting 10 Minutes, on October 30, 2020. In that meeting and as documented in those minutes, Ethicon emphasized that such practices needed to be addressed for Milestone 1B; however, as outlined, errors due to such practices still exist in the final report for VAB. These errors are systematic and cannot be remedied by simply re-running the data and re-generating another report; rather, previously completed labs, data collection, and annotation processes would need to be reworked and repeated. Additionally, on June 20, 2022, Ethicon and CI met during which Ethicon indicated to CI that the program would be at high risk of cancellation if the program

Confidential

CONFIDENTIAL

PX-3

DEF_0072278
Page 2 of 3

Pursuant to Section 10.3.2(a) of the Research, Development, License and Commercialization Agreement between Ethicon, Inc. ("Ethicon") and ChemImage, Corporation ("CI") effective as of December 27, 2019 (the "Agreement"), Ethicon is hereby providing notice to CI via this letter of its intent to terminate the Agreement for cause for failure to achieve a Development Milestone, which constitutes a Material Breach. In particular, a final report provided on December 16, 2022, for a subset of the critical structures, veins, arteries, and bile ducts (collectively, "VAB") that are a part of Milestone 1B in the Agreement, is not evaluable. In fact, several errors and flaws in collecting and processing data were identified upon review of the final report. Specifically, uncertainty with respect to negative controls, use of omnipresent ignore labels, and data discrepancies between a preliminary report and the final report amongst others have been identified. With respect to "The final report [...] is not evaluable." was done contrary to the process proposed and agreed upon in data review board meetings and without review by Ethicon. Further, pursuant to the Agreement, Ethicon had a third party review the final report and underlying data examples provided and the third party concluded that as a direct result of the implementation of ignore labels, there is a significant risk that the metrics are misleading indicators of performance and that the final report cannot be evaluated on the basis of these metrics.

3/6/23 Termination Letter (PX-3)

PX-3 at 2

Ethicon Has Never Taken the Position That ChemImage Failed on the Metrics



Dr. Steen Hansen

*Director, Advanced
Visualization Technologies,
Ethicon & Ethicon's Project
Erie Technical Lead*

Q. Does it say, for example, that it didn't achieve 80 percent sensitivity or 80 percent specificity?

A. No.

Q. Am I right, sir, that there's no study or analysis or data that Ethicon ever delivered to ChemImage showing that the Project Erie study failed to meet these performance criteria at an 80 percent level for sensitivity or specificity?

A. No.

Q. No, meaning that no such report was ever delivered, true?

A. In terms of the 80/80?

Q. Yes.

A. No.

Tr. 749:1-12 (Hansen)

Ethicon Has Never Taken the Position That ChemImage Failed on the Metrics



Tamara Lanier

*Director, Sales Excellence
and Enablement, Ethicon &
Project Erie JSC Member*

Q. Yes or no to my question, Ms. Lanier. You do not say in this termination letter that my client, ChemImage, failed to meet the performance metrics, right?

THE COURT: Yes or no.

A. I do not say. So yes, I do not say. No, I do not say. I'm sorry. I'm not trying to be difficult. I just don't know which one is the yes or the no. Can I restate the answer? No, I do not say those things.

Q. Would you like me to restate the question, your Honor?

THE COURT: No. I think they answered the question that those things are not stated in the letter; is that correct?

THE WITNESS: That's correct.

Tr. 575:5-575:17 (Lanier)

If Ethicon Could Have Said That ChemImage Failed the Performance Metrics, It Would Have

Dr. Steen Hansen

Director, Advanced Visualization Technologies,
Ethicon & Ethicon's Project Erie Technical Lead



Structure	Obscuration	Performance Metrics	
		Sens	Spec
Artery Artery 50 mm WD	0 (Unobscured)	85.8±28.2	91.9± 8.0
	>0 – 1	90.2±20.3	92.3± 4.7
	>1 – 2.5	70.0±30.6	91.5± 4.9
	>2.5 – 5	92.4±10.3	89.7±12.6
	>5 -7.5	48.3±21.3	96.1± 3.7
	>7.5 – 10	-	-
	>10	-	-
Vein 50 mm WD	0 (Unobscured)	94.1±17.4	90.2± 4.9
	>0 – 1	79.1±26.4	93.1± 3.9
	>1 – 2.5	90.0±17.7	88.7± 7.7
	>2.5 – 5	51.5±45.8	84.0± 2.1
	>5 -7.5	97.0± 1.7	89.2± 1.4
	>7.5 – 10	-	-
	>10	-	-
Bile Duct 80 mm WD	0 (Unobscured)	95.6± 8.9	86.7± 6.5
	>0 – 1	-	-
	>1 – 2.5	91.7± 7.3	91.9± 4.4
	>2.5 – 5	88.8±12.7	93.8± 5.0
	>5 -7.5	-	-
	>7.5 – 10	-	-
	>10	-	-

Q. Okay. When you received this in December of 2022, you didn't immediately contact ChemImage and say, you failed to meet milestone 1B because some of the levels of obscuration didn't meet the 80 percent threshold, correct?

A. **Correct, we were doing a thorough review of the whole work.**

Q. Well, if in fact it were true that you believe they had to meet the 80 percent threshold for each level of obscuration, it would have been obvious to you from the face of this document that they didn't with respect to a couple categories, right?

A. **That was also what my team and I discussed in early January when we met after the Christmas holiday. [...]**

Q. You didn't take the position in December, in January or even in your March termination letter that ChemImage had to meet the stratification -- it had to meet the 80 percent performance criteria for each individual layer of obscuration, correct?

A. **No. Because the problem was –**

Tr. 829:12-22; 830:5-10 (Hansen)

Whatever Data Ethicon Requested, ChemImage Provided



Dr. Patrick Treado

*Founder & President,
ChemImage*

& JSC Member, Project Erie

A. No. ChemImage would provide data to Ethicon whenever it was requested. And in providing data, the data would include the ignore labels, the annotated results. And so by providing data to the algorithm, the respective algorithm teams, including Kitware, we were providing indication of the prevalence of ignore labels because they were reflected in the data themselves.

Tr. 70:13-19 (Treado)



Dr. Steen Hansen

*Director, Advanced
Visualization Technologies,
Ethicon & Ethicon's Project
Erie Technical Lead*

Q. Mr. Hansen, is there any data that you asked or your team asked ChemImage to provide that ChemImage didn't provide?

A. Can you elaborate the question.

Q. Can you answer my question. Do you recall any instance in 2022 where you ask ChemImage for data and they refused to provide it to you?

A. No.

Tr. 746:18-24 (Hansen)

ChemImage Worked Daily And Transparently With Ethicon

Erie Program Calendar July 2022

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
3	4	5	6	7	8	9
Zeus Sprint A Week	Holiday 4 JULY	Erie Schedule 9AM CL Weekly 10:30AM A/V Networking 11AM Erie SW Tue Mtg 1PM	9AM GT Review EL5 Erie Integration Meeting 12:30PM	CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM	DL Monthly 12PM	
10	11	12	13	14	15	16
Zeus Sprint B Week	EL5 UBN 2 LL 9:30	Erie Schedule 9AM CL Weekly 10:30AM Erie SW Tue Mtg 1PM	Erie Integration Meeting 12:30PM	PMM 12PM CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM	CL1/CL2 TRR	
17	18	19	20	21	22	23
Zeus Sprint A Week	LabCorp 4pm	Erie Schedule 9AM CL Weekly 10:30AM Erie SW Tue Mtg 1PM Monthly Erie Strategy Connection 1PM	Erie Integration Meeting 12:30PM	PMM 12PM CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM	EL6 TRR	
24	25	26	27	28	29	30
Zeus Sprint B Week		CL1:Pilot Study Erie Schedule 9AM Erie SW Tue Mtg 1PM	CL1:Pilot Study CL2:Shipment Erie Integration Meeting 12:30PM	Q3/2022 pre-planning event 9:30 PMM 12PM CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM		
31	1	2	3	4	5	6
EL6 Study Zeus Sprint A Week	EL6 Study LabCorp 4pm	EL6 Study - CL3:Inoculation Erie Schedule 9AM CL Weekly 10:30AM JSC Meeting 12PM Erie SW Tue Mtg 1PM	EL6 Study	EL6 Study CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM	EL6 Study	



06/30/22 Weekly Erie PM
Meeting Presentation (PX-704)

PX-704 at 14

ChemImage Worked Daily And Transparently With Ethicon

Erie Program Calendar August 2022

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
31 EL6 Study Zeus Sprint A Week	1 EL6 Study LabCorp 4pm	2 EL6 Study Erie Schedule 9AM CL Weekly 10:30AM JSC Meeting 12PM Erie SW Tue Mtg 1PM	3 EL6 Study CL3:Inoculation	4 EL6 Study CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM	5 EL6 Study	6
7 Zeus Sprint B Week	8 CL2:Lung	9 CL2:Lung Erie Schedule 9AM CL Weekly 10:30AM Erie SW Tue Mtg 1PM	10 CL2:Lung Erie Integration Meeting 12:30PM	11 CL2:Lung PMM 12PM CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM	12 DL Monthly 12PM	13
14 Zeus Sprint A Week	15 LabCorp 4pm	16 Erie Schedule 9AM CL Weekly 10:30AM Monthly Erie Strategy Connection 1PM Erie SW Tue Mtg 1PM	17 Erie Integration Meeting 12:30PM	18 PMM 12PM CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM	19 EL6 LL EL 7 TRR	20
21 Zeus Sprint B Week	22	23 CL4:Inoculation Erie Schedule 9AM CL Weekly 10:30AM JSC Meeting 12PM Erie SW Tue Mtg 1PM	24 Erie Integration Meeting 12:30PM	25 PMM 12PM CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM	26 CL1/CL2 LL CL3 TRR	27
28 EL7 Study Zeus Sprint A Week	29 EL7 Study CL3:Shipment LabCorp 4pm	30 EL7 Study Erie Schedule 9AM CL Weekly 10:30AM Erie SW Tue Mtg 1PM	31 EL7 Study Erie Integration Meeting 12:30PM	1 EL7 Study CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM	2 EL7 Study	3



06/30/22 Weekly Erie PM
Meeting Presentation (PX-704)

PX-704 at 15

ChemImage Worked Daily And Transparently With Ethicon

Erie Program Calendar Sept 2022

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
28	29	30	31	1	2	3
EL7 Study Zeus Sprint A Week	EL7 Study LabCorp 4pm	EL7 Study Erie Schedule 9AM CL Weekly 10:30AM Erie SW Tue Mtg 1PM	EL7 Study Erie Integration Meeting 12:30PM	EL7 Study CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM	EL7 Study	
4	5	6	7	8	9	10
Zeus Sprint B Week	LABOR DAY	CL3 Erie Schedule 9AM CL Weekly 10:30AM Erie SW Tue Mtg 1PM	CL3 Erie Integration Meeting 12:30PM	CL3 PMM 12PM CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM		
11	12	13	14	15	16	17
Zeus Sprint A Week	LabCorp 4pm	Erie Schedule 9AM CL Weekly 10:30AM Erie SW Tue Mtg 1PM	CL4:Shipment Erie Integration Meeting 12:30PM	PMM 12PM CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM	EL7 LL CL4/CL5 TRR	
18	19	20	21	22	23	24
Zeus Sprint B Week		Erie Schedule 9AM CL Weekly 10:30AM Monthly Erie Strategy Connection 1PM Erie SW Tue Mtg 1PM	Erie Integration Meeting 12:30PM	PMM 12PM CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM	CL3 LL	
25	26	27	28	29	30	1
Zeus Sprint A Week	CL4 LabCorp 4pm	CL4 JSC Meeting 12PM CL Weekly 10:30AM Erie Schedule 9AM Erie SW Tue Mtg 1PM	CL4 Erie Integration Meeting 12:30PM	CI - Hardware Weekly Connect 1PM Erie/AICS 2:30PM		



06/30/22 Weekly Erie PM
Meeting Presentation (PX-704)

PX-704 at 16

Ethicon Had Ample Time to Review the Data

CS VAB Q3 Interim Report: Video Review Instructions

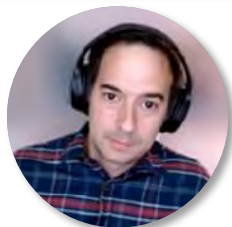
1. Locate the excel document for entering your reviews and save a local version. *Do not save them to the document on Sharepoint.*
 - Sharepoint link Excel: [VideoReviewRanking_Q3Report_ReviewerDoc_Rev1.xlsx](#)
2. Review each video and provide a ranking for all targets in the scene.
 - Combinations: Bile duct & cystic artery, vein & artery, vein only, artery only, bile duct only
 - Note: Target only videos may contain the counterpart target, but they could not be resolved confidently by the ground truth team or surgeons and are ignored.
3. Return populated excel document to CI and Cambridge for independent compilation of results and de-identifying reviewer names by Oct 14, 2022.
 - CI: Alyssa Zrimsek zrimseka@chemimage.com
 - Cambridge: Sylvain Jamais sylvain.jamais@cambridgeconsultants.com
 - CI will prepare a readout of the aggregated video review results for the PMM on Oct 20th if all of the reviews have been submitted by the deadline.



PX-867 (Q3 VAB Interim Report: Video Review)

PX-867 at 6

Ethicon's Erie Technical Team Understood the Purpose and Application of Ignore Labels



Murat Aksoy

Principal Algorithms Engineer, Ethicon



Joe Corrigan



Rishi Jobanputra

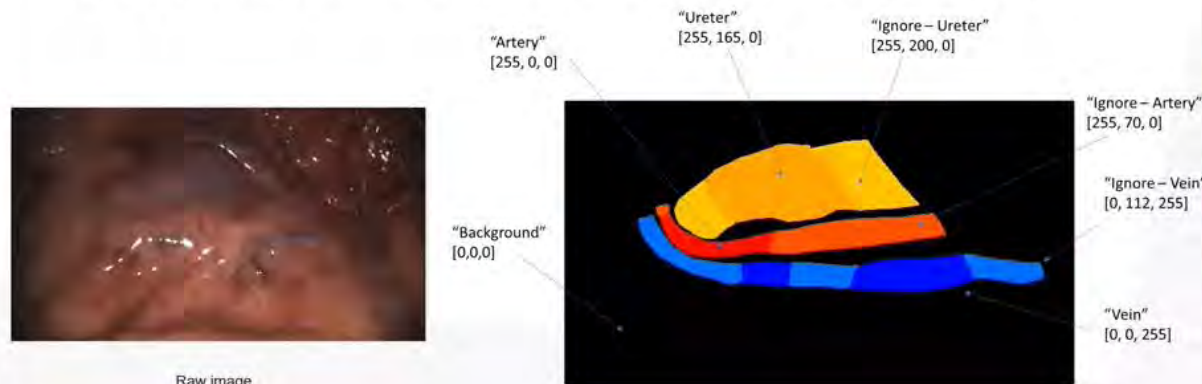


Rupert Thomas



Image analysis (2)

- The labels and rgb values shown are from constants.CATALOG_RGB_CODES
- Is there a link between vessel obscuration/degree and whether or not it is designated as "ignore"?



4 Oct 2022 P4292-P-034 v0.0w Commercially Confidential

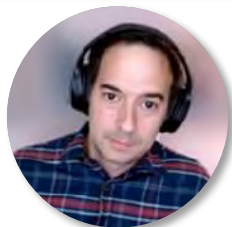
EB1U5_EL6_01_5041, Scene 3

10

16:04 Rishi Jobanputra: What we see is obviously
16:05 there's an example of -- we see different shading.

October 5, 2022 Weekly Cambridge Algorithm Analysis Meeting (PX-378) at 19:24-22:36

Ethicon's Erie Technical Team Understood the Purpose and Application of Ignore Labels



Murat Aksoy

Principal Algorithms Engineer, Ethicon



Joe Corrigan



Rishi Jobanputra

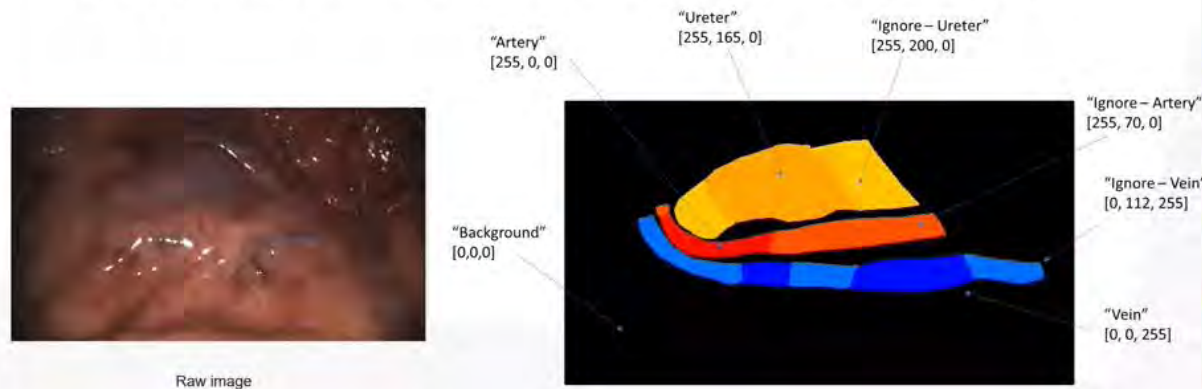


Rupert Thomas



Image analysis (2)

- The labels and rgb values shown are from constants.CATALOG_RGB_CODES
- Is there a link between vessel obscuration/degree and whether or not it is designated as "ignore"?



4 Oct 2022 P4292-P-034 v0.0w Commercially Confidential

EB1U5_EL6_01_5041, Scene 3

10

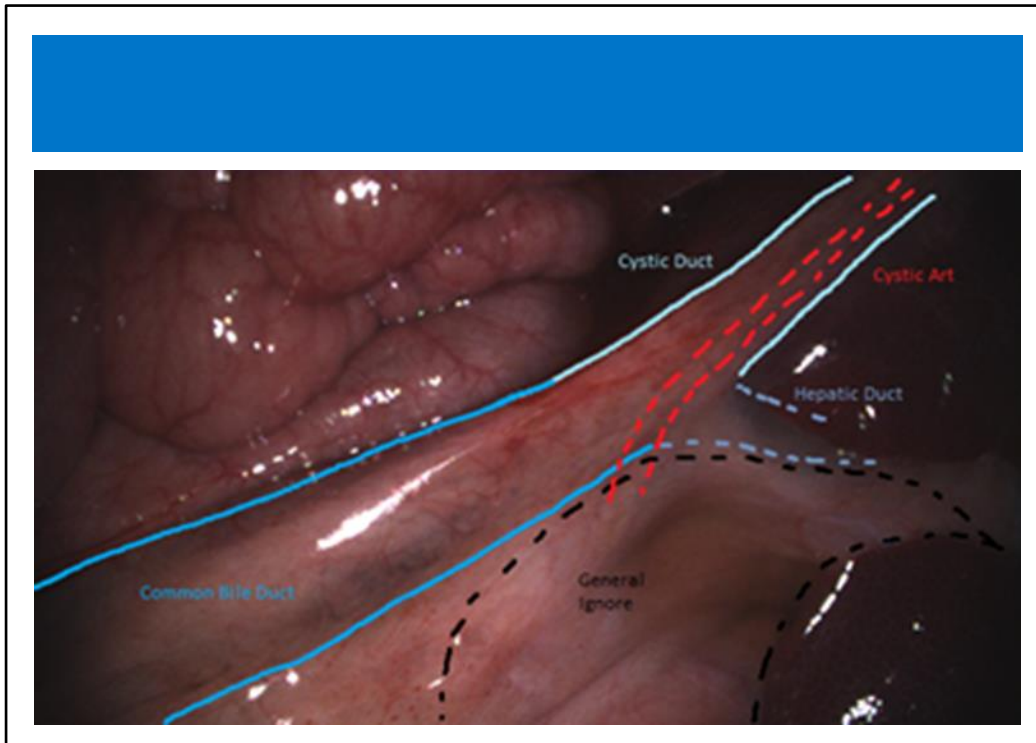
21:17 Murat Aksoy [ETH]: Yeah, yeah, I mean it's also a
21:18 different thing to say that there is an obscure vein

October 5, 2022 Weekly Cambridge Algorithm Analysis Meeting (PX-378) at 26:01-27:02

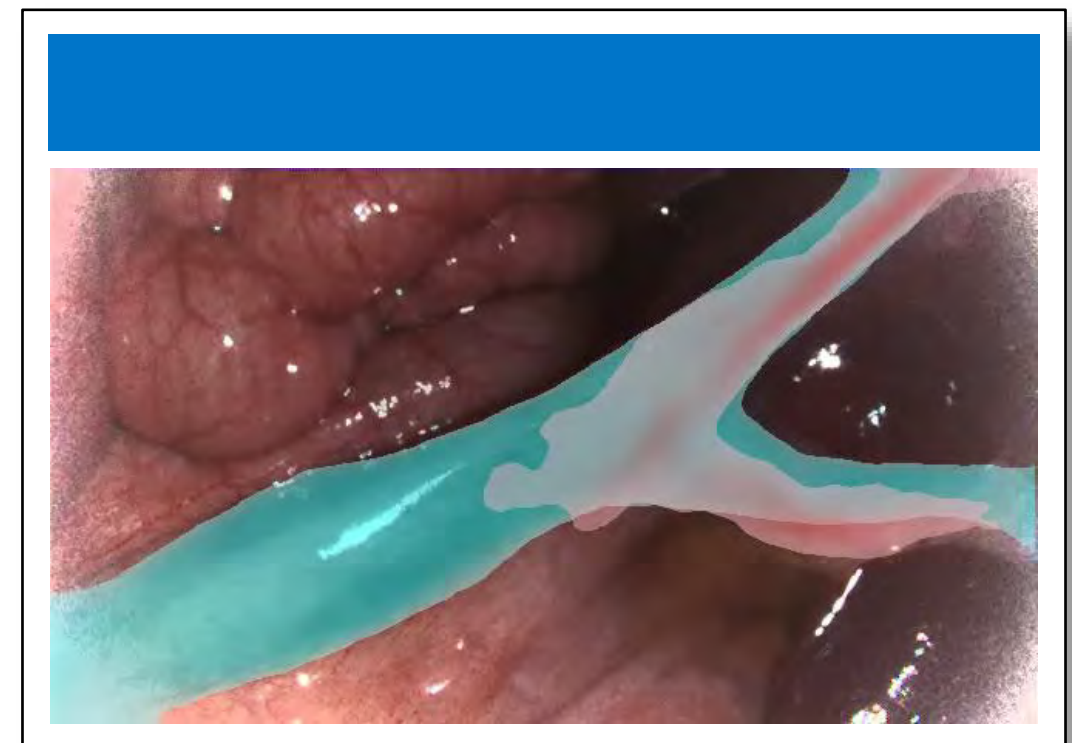
CS VAB Q3 Interim Report Video Review That Ethicon Participated in Shows Application of Ignore Labels

Slide #	Target	Reviewer Notes
26	Bile Duct	Wonderful, some inconsistency along hepatic but it is obscured

PX-429



PX-867 at p. 27 of 115 (slide 26)

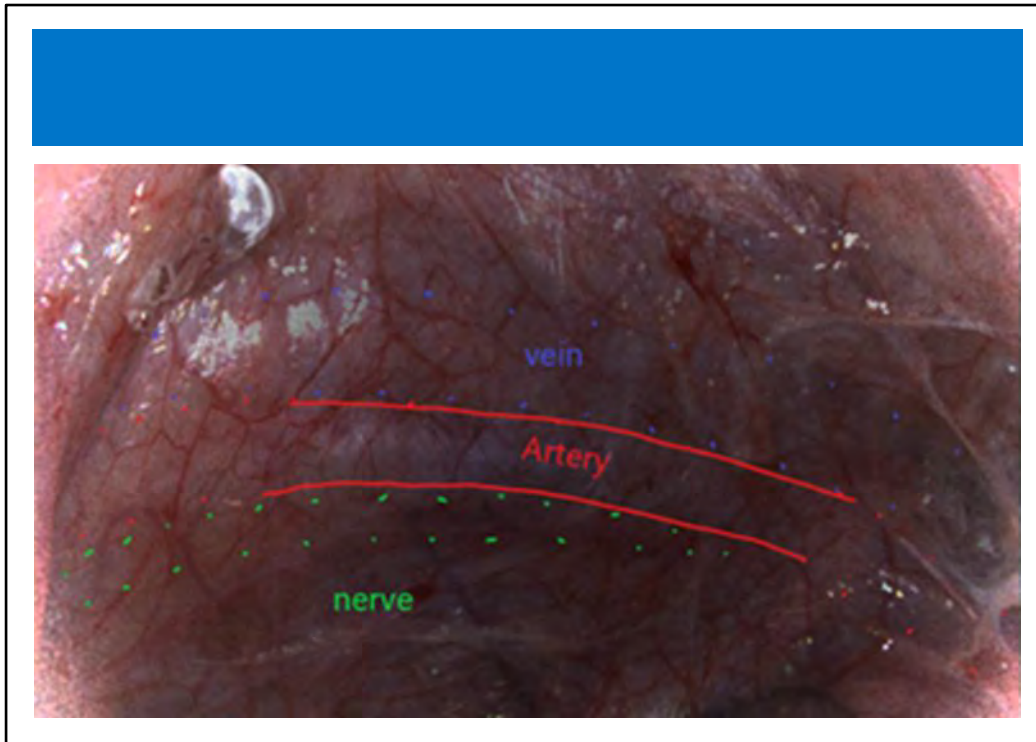


PX-867 at p. 27 of 115 (slide 26)

CS VAB Q3 Interim Report Video Review That Ethicon Participated in Shows Application of Ignore Labels

Slide #	Target	Reviewer Notes
114	Artery	None-great way to finish

PX-429



PX-867 at p. 115 of 115 (slide 114)



PX-867 at p. 115 of 115 (slide 114)

Ethicon Never Analyzed or Even Looked at the Underlying Data for the VAB Report



Dr. Steen Hansen

*Director, Advanced
Visualization Technologies,
Ethicon & Ethicon's Project
Erie Technical Lead*

Q. And the reference is EL5_04_5055, for example, those are references to particular run files that you could go and check for yourself, right?

A. I don't know. I never went into the actual data, but I would assume so, yes.

Tr. 756:3-7 (Hansen)

With respect to the data underlying the final VAB Report:

Q. Okay. Did you go back and review the 800 run files yourself?

A. No.

Q. Okay. You had the opportunity to do that, did you not?

A. I don't know. I didn't go into those data.

Tr. 826:1-5 (Hansen)

Ethicon Has No Data to Backup Its Position



Dr. Steen Hansen

*Director, Advanced
Visualization Technologies,
Ethicon & Ethicon's Project
Erie Technical Lead*

Q. As of January 26, you didn't tell ChemImage that you thought that the VAB final report was unevaluable, right?

A. No, not at that time. No.

Trial Tr. at 811:6-8 (Hansen)

Q. Okay. There is nothing that you gave to ChemImage, nothing that you provided that we can see in the court in this case that describes what data analysis or evaluation you did to reach the conclusion that the VAB final report was not evaluable, true?

A. Yes.

Trial Tr. at 814:8-13 (Hansen)

Dr. Hansen's Termination Memo Is Cloaked in Privilege

Privilege Document Numl	Date Sent	Date Last Modified	Parent Date	Custodians	Document Type	Author/From	Last Author	Recipients	CC	BCC	Thread Participant	Additional Attorney	Privilege Claim	Privilege Descriptio
PL000000470	1/26/23		1/26/23	Hansen, Steen	Email	Steen Hansen		Hilary Reinhardt*			Hilary Reinhardt*; Richard Gooding; Steen Hansen; Tamara Lanier; Trey Rees*	Trey Rees*;Hilary Reinhardt*	Attorney Client	Email thread providing information requested by counsel and necessary for counsel to render legal advice regarding contract matters.
PL000000471		1/26/23	1/26/23	Hansen, Steen	Document	Steen Hansen	Steen Hansen					Trey Rees*;Hilary Reinhardt*	Attorney Client	Summary reflecting counsel's legal advice regarding contract matters.

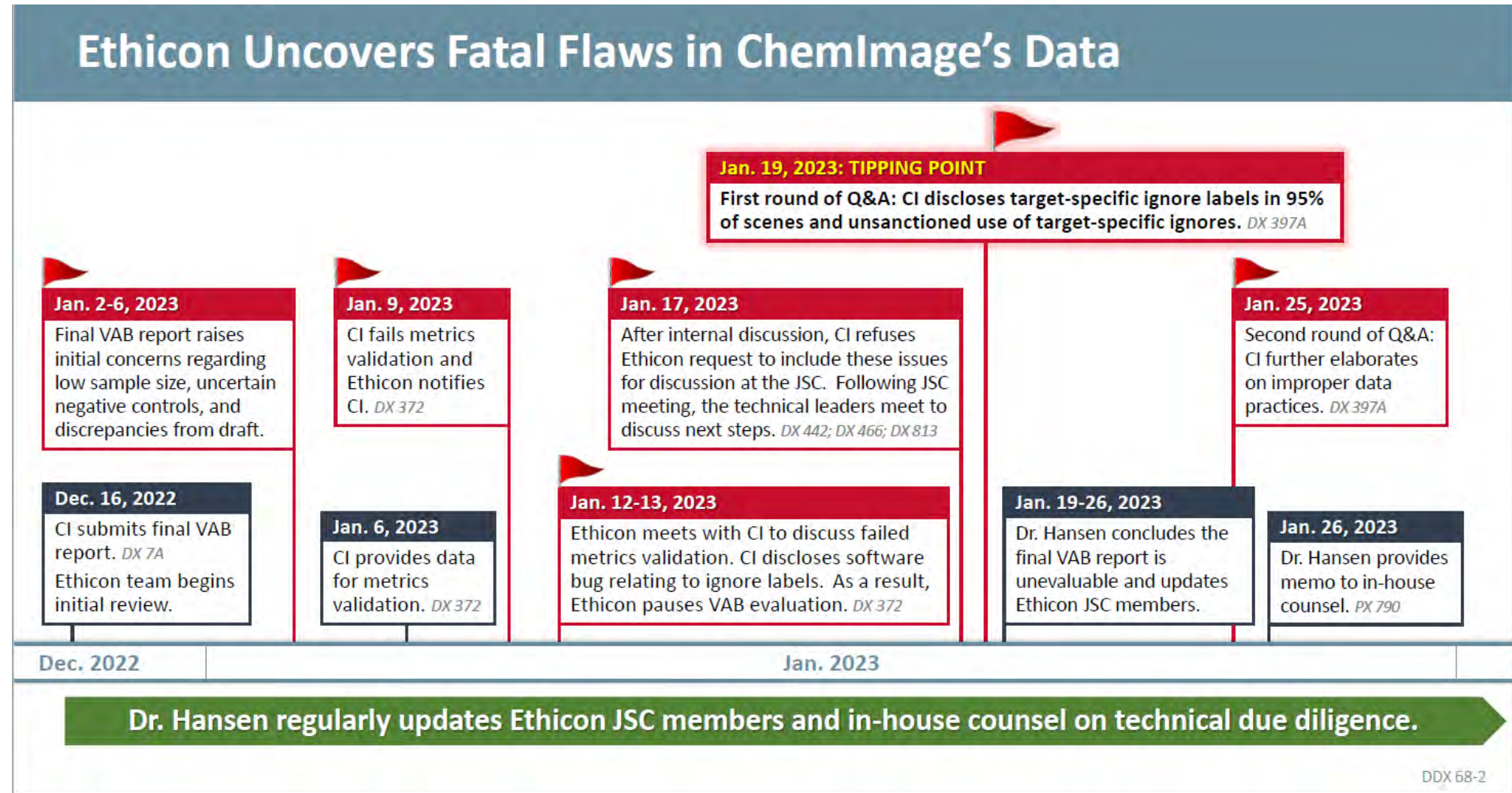
Author/From
Steen Hansen
Steen Hansen

Recipients
Hilary Reinhardt*

Privilege Descriptio
Email thread providing information requested by counsel and necessary for counsel to render legal advice regarding contract matters.
Summary reflecting counsel's legal advice regarding contract matters.

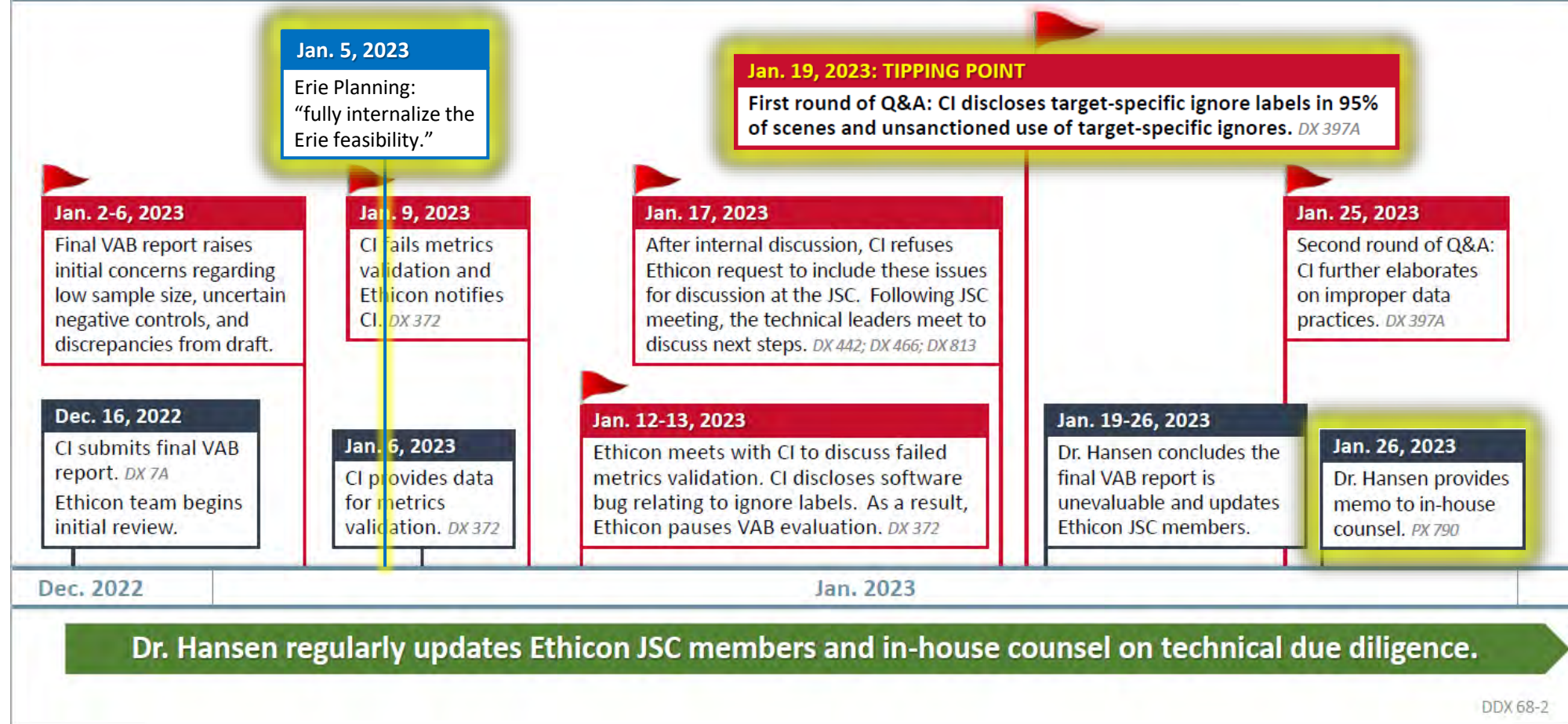
PX-790 (Defendants' Amendment Privilege Log) at PL000000470, PL000000471

Ethicon's Timeline Reveals the Absence of Any Good Faith Analysis of M1B VAB Data



By January 2023, Ethicon Already Planned to Internalize Erie

Ethicon Uncovers Fatal Flaws in ChemImage's Data



Each of the Three Bases From the Termination Letter Fails

[1] “uncertainty with respect to negative controls,”

[2] “use of omnipresent ignore labels,”

[3] “data discrepancies between a preliminary report and the final report”

Pursuant to Section 10.3.2 of the Research, Development, License and Commercialization Agreement between Ethicon, Inc. (“Ethicon”) and ChemImage Corporation (“CI”) effective as of December 27, 2019 (the “Agreement”), Ethicon is hereby providing notice to CI via this letter of its intent to terminate the Agreement for cause for failure to achieve a Development Milestone, which constitutes a Material Breach of the Agreement, for a subset of the critical structures for a subset of the critical structures. The final report for Milestone 1B in the Agreement, is not evaluable. In fact, several errors and flaws in collecting and processing data were identified upon review of the final report. Specifically, uncertainty with respect to negative controls, use of omnipresent ignore labels, and data discrepancies between a preliminary report and the final report, amongst others have been identified. With respect to ignore labels, the process of using such labels was done contrary to the process proposed and agreed upon in data review board meetings and without review by Ethicon. Further, pursuant to the Agreement, Ethicon had a third party review the final report and underlying data examples provided and the third party concluded that as a direct result of the implementation of ignore labels, there is a significant risk that the metrics are misleading indicators of performance and that the final report cannot be evaluated on the basis of these metrics.

ETHICON

PART OF THE ~~Johnson & Johnson~~ FAMILY OF COMPANIES
Ethicon, Inc.
a Johnson & Johnson company
U.S. Route 22 West
Somerville, NJ 08876

March 6, 2023

ChemImage Corporation
7325 Penn Avenue, Suite 200
Pittsburgh, PA 15208

ATTN: Matthew Nelson, Chief Technology Officer, and Chief Operating Officer

Re: RESEARCH, DEVELOPMENT, LICENSE AND COMMERCIALIZATION AGREEMENT

Dear Matthew and Chief Operating Officer:

Pursuant to Section 10.3.2(a) of the Research, Development, License and Commercialization Agreement between Ethicon, Inc. (“Ethicon”) and ChemImage Corporation (“CI”) effective as of December 27, 2019 (the “Agreement”), Ethicon is hereby providing notice to CI via this letter of its intent to terminate the Agreement for cause for failure to achieve a Development Milestone, which constitutes a Material Breach. In particular, a final report provided on December 16, 2022, for a subset of the critical structures, veins, arteries, and bile ducts (collectively, “VAB”) that are a part of Milestone 1B in the Agreement, is not evaluable. In fact, several errors and flaws in collecting and processing data were identified upon review of the final report. Specifically, uncertainty with respect to negative controls, use of omnipresent ignore labels, and data discrepancies between a preliminary report and the final report, amongst others have been identified. With respect to ignore labels, the process of using such labels was done contrary to the process proposed and agreed upon in data review board meetings and without review by Ethicon. Further, pursuant to the Agreement, Ethicon had a third party review the final report and underlying data examples provided and the third party concluded that as a direct result of the implementation of ignore labels, there is a significant risk that the metrics are misleading indicators of performance and that the final report cannot be evaluated on the basis of these metrics.

Ethicon previously communicated its concerns with the collecting and data processing practices used by CI for Milestone 1A in JSC Meeting 10 which was documented in writing by the parties in the JSC Meeting 10 Minutes, on October 30, 2020. In that meeting and as documented in those minutes, Ethicon emphasized that such practices needed to be addressed for Milestone 1B; however, as outlined, errors due to such practices still exist in the final report for VAB. These errors are systematic and cannot be remedied by simply re-running the data and re-generating another report; rather, previously completed labs, data collection, and annotation processes would need to be reworked and repeated. Additionally, on June 20, 2022, Ethicon and CI met during which Ethicon indicated to CI that the program would be at high risk of cancellation if the program

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PX-3

DEF_0072278
Page 2 of 3

3/6/23 Termination Letter (PX-3)

PX-3 at 2

Ethicon's Concerns About Negative Controls and Data Discrepancies Are Trivial

[1] “uncertainty with respect to negative controls,”

[3] “data discrepancies between a preliminary report and the final report”

Agre
Dece

its intent to terminate the Agreement for cause for failure to achieve a Development Milestone, which constitutes a Material

for a subset of the critical stru
part of Milestone 1B in the
collecting and processing da
uncertainty with respect to

discrepancies between a preliminary report and the final report, amongst others have been identified. With respect to ignore labels, the process of using such labels was done contrary to the process proposed and agreed upon in data review board meetings and without review by Ethicon. Further, pursuant to the Agreement, Ethicon had a third party review the final report and underlying data examples provided and the third party concluded that as a direct result of the implementation of ignore labels, there is a significant risk that the metrics are misleading indicators of performance and that the final report cannot be evaluated on the basis of these metrics.

ETHICON

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Ethicon, Inc.
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U.S. Route 22 West
Somerville, NJ 08876

March 6, 2023

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7325 Penn Avenue, Suite 200
Pittsburgh, PA 15208

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Ethicon previously communicated its concerns with the collecting and data processing practices used by CI for Milestone 1A in JSC Meeting 10 which was documented in writing by the parties in the JSC Meeting 10 Minutes, on October 30, 2020. In that meeting and as documented in those minutes, Ethicon emphasized that such practices needed to be addressed for Milestone 1B; however, as outlined, errors due to such practices still exist in the final report for VAB. These errors are systematic and cannot be remedied by simply re-running the data and re-generating another report; rather, previously completed labs, data collection, and annotation processes would need to be reworked and repeated. Additionally, on June 20, 2022, Ethicon and CI met during which Ethicon indicated to CI that the program would be at high risk of cancellation if the program

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PX-3

DEF_0072278
Page 2 of 3

3/6/23 Termination Letter (PX-3)

PX-3 at 2

ChemImage's Technology May Have Been Outperforming Surgeons in Negative Control Scenes



Dr. Steen Hansen

*Director, Advanced
Visualization Technologies,
Ethicon & Ethicon's Project
Erie Technical Lead*

Q. And you give an example in reviewing the final VAB report: "One particular glaring example of this was a purported artery negative control scene that contained a strong detection - without a corresponding ground truth annotation." Do you see that?

A. Yes.

Q. And when you say a strong detection, what you are referring to is the detection that was made by the project Erie technology, right?

A. Yes.

Q. Okay. So the spectroscopy plus the AI detected something in the scene -- in a scene where the surgeons didn't identify a critical structure, correct?

A. That was how it looked, yes.

Tr. 752:4-17 (Hansen)

Ethicon Never Looked at the Negative Control Scenes It Terminated the Agreement Over



Dr. Steen Hansen

Director, Advanced Visualization Technologies, Ethicon & Ethicon's Project Erie Technical Lead

Q. In slide 61 [of the VAB Final Report], it indicates that of the total of 1071 run files, 168 were designated as negative controls ... did you check the issues, the issues that you found with negative controls that appear to have structures in them? Did you check how pervasive that was across the 168 negative controls that ChemImage designated?

A. We didn't have access to that data, that was up to ChemImage to provide that to us.

Q. Did you request all of those negative controls so you could analyze them?

A. No.

Hansen Dep. Tr. 121:20-122:15



Dr. Ricardo Estape

Defendants' Clinical Expert

Q. ... [Y]our opinion is that the negative control scenes that ChemImage used actually did include the structures that were supposed to be detected by the technology; correct?

A. Correct. ...

Q. How many of the negative control scenes [in the VAB Final Report] have those structures present?

A. ... I don't remember an exact number at this time.

...

Q. ... And you didn't identify more than one example [of false positives in a negative control area] in your report either; correct?

A. I showed one example.

Estape Dep. Tr. 364:1-365:24

Ethicon Identified One “Data Discrepancy” Between the VAB Interim and Final Report



Dr. Steen Hansen

*Director, Advanced
Visualization Technologies,
Ethicon & Ethicon's Project
Erie Technical Lead*

Q. The only discrepancy that you actually identify is change to a single slide. Isn't that right?

A. Yes, that's how I remember it.

Tr. 750:11-13 (Hansen)

“Negative Control” and “Data Discrepancy” Claims Fail Under VAB Criteria

Erie Program CS M1B VAB Acceptance Protocol Reflecting VAB Performance Requirements (2-Dec-2022)

Detection Performance Metrics

- Characterize
- Negative Control Scenes: Show additional 10% (of total demonstrated N) to detection scenes (e.g., Bile Duct in Neck scene)

VAB Final Report (PX-768) at 17

CS VAB Final Report

Summary of Negative Controls

Target	Number of Files	Number of NC Files	Total Files	Percent NC
Artery	729	24	753	3.2%
Vein	633	54	687	7.9%
Bile Duct	229	128	357	35.9%
All Targets	1071	168	1239	13.6%

VAB Final Report (PX-768) at 62

Ethicon's Complaints About Ignore Labels Fail Comprehensively

ETHICON

ETHICON, INC.
a Johnson & Johnson company
U.S. Route 22 West
Somerville, NJ 08876

March 6, 2023

ChemImage Corporation
7325 Penn Avenue, Suite 209
Pittsburgh, PA 15208

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PX-3

DEF_0072278
Page 2 of 3

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3/6/23 Termination Letter (PX-3)

PX-3 at 2

Ethicon Agrees That There Is Uncertainty in Determining Ground Truth for Live Tissue



Dr. Steen Hansen

*Director, Advanced
Visualization Technologies,
Ethicon & Ethicon's Project
Erie Technical Lead*

Q. Would you agree with me, Dr. Hansen, that obscured scenes also have uncertainty associated with them?

A. Yes.

Q. In fact, they can have more uncertainty because elements of the structures are obscured?

A. Yes.

Tr. 823:9-14 (Hansen)

Ethicon's Surgeons Encountered Uncertainty in the Surgical Suite



Kevin Lewis

*Principal Scientist for
Preclinical Research, Ethicon
& Manager of Preclinical
R&D for Project Erie*

Q. In this scene, is there uncertainty?

A. So you have obscured structures, which can have uncertainty.

Tr. 948:17-19 (Lewis)

Everyone Agrees There Is Inherent Uncertainty in Labelling Live Tissue



Dr. Adam Saltman
*Chief Medical Officer,
ChemImage*

Q. Now, when looking at these scenes, is it possible for you to ever be 100 percent certain about every pixel in that scene?

A. **No, it's not. And particularly, as you can see, the scene moves from frame to frame, so there's always uncertainty. You try the best you can to reduce it as much as you can, but you're never going to get to 100 percent.**

Tr. 217:19-217:24 (Saltman)

23. Even with the help of ultrasound, however, in many cases it was not possible to be 100% certain of ground truth for an entire scene. For example, one cause of uncertainty is the fact that obscured critical structures in a living body, of course, do not remain at a constant depth, nor are they static in space. An artery may appear ("surface") briefly in a scene only to retreat under deeper layers of fat, tissue, or another structure such as the gall bladder. In this particular example, it would not be possible, even with the use of ultrasound, to see the exact contours of the artery as it undulates, particularly once it passes deeper into the body or behind another structure. In such cases where it was not possible to identify the exact contours of a critical structure with certainty, or where it was possible to establish ground truth only for part of a structure in the FOV, we would note our uncertainty for the data annotators, which means that just that part of the scene should be "ignored." This could result in a scene where most of the

PX-1019 (Saltman Aff.) ¶ 23

The Parties' Process for Determining Ground Truth Was Comprehensive

Conduct Erie Lab

1 Perform Surgery



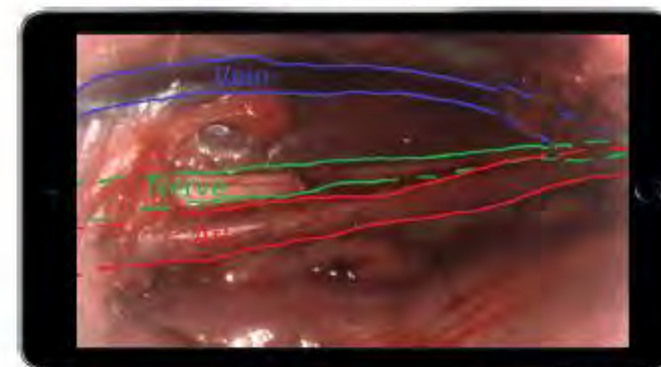
PX-1002A at Slide 18

2 Discuss Ground Truth



PX-1002A at Slide 64

3 Annotate



PX-214A at 74

The Parties' Process for Determining Ground Truth Was Comprehensive



Dr. Adam Saltman
Chief Medical Officer,
ChemImage

"In these later labs, ***the Ethicon surgical team, the ChemImage ground truth team, and I would discuss the annotations of a representative image of each run file. This narration was recorded. The Ethicon surgeons and I would then reach consensus on ground truth in each of those scenes, in real time,*** rather than weeks after a lab. The discussion regarding this new, refined workflow took place during the lab itself and was memorialized in our EL4 LL meeting. ***The reaction from both teams was overwhelmingly positive;*** the Ethicon attendees—in particular the surgeons and veterinarians with whom I was performing the procedures—wholeheartedly supported my recommendation to resolve questionable ground truth in realtime."

PX-1019 (Saltman Aff.) ¶ 35

Defendants' Expert Supports Real-Time Ground Truth Determination



Dr. Ricardo Estape
Defendants' Clinical
Expert

Q. You would agree with me that ***determining the ground truth during the labs is more effective than doing so at a later time after the lab is complete?***

A. ***Absolutely.*** It's the only way.

Tr. 1009:24-1010:2 (Estape)

Uncertainty Makes It Impossible to Positively Identify Every Pixel in a Scene



Joe Corrigan

*Head of Technology for
Cambridge Consultants'
Intelligent Services and
Healthcare Business*

Q. Well, if there's ground truth uncertainty, it is not feasible to correctly annotate pixels where there's ground truth uncertainty. Do you agree with that, sir?

A. That's true.

Tr. 901:24-902:2 (Corrigan)

A Data Collection Strategy Should Consider Both Quantity and Quality of Data



Dr. Daniel Sodickson
Plaintiff's Expert

- Q. So why can't surgeons or doctors use techniques that we've heard of in this case, like dissection and ultrasound; why can't they use that to get a perfect ground truth for a scene?
- A. **So I think there are two main reasons. One we heard talked about in some of the testimony yesterday that the body is moving as you're trying to assess it. So even if you can nail something with, say, an ultrasound, it might have moved in the next frame, or you might even be moving with it ultrasound transducer or with dissection or anything else. But I think an even greater question is that these other approaches for establishing ground truth generally take a fair amount of time and effort. And so, there's a point of diminishing returns. If you are spending all this time getting 5 percent better ground truth, you are missing out on entire new scenes which could bring in a whole lot more useful data and ultimately much more valuable to the project.**

Tr. 276:20-277:10 (Sodickson)